

WALTER G. TALAREK, P.C.

1008 Riva Ridge Drive
Great Falls, VA 22066
USA

TEL: (703) 759-4837

FAX: (703) 759-5548

TO: Ms. Joan Karrie
Bio-Pesticides and Pollution Prevention Division (7501W)

COMPANY: Environmental Protection Agency

DATE: March 14, 1996

FAX NO.: (703) 308-7026

PAGES: 5

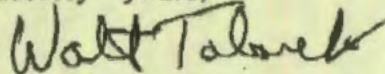
Dear Joan:

I am forwarding revised pages 3 of 5 and 4 of 5 to Volume 3 of Neudorff's application for registration of NEU 1165M Slug and Snail Bait. This volume is titled "Analysis and Certification of Ingredients". These revisions are in response to your request of yesterday that Neudorff check its figures in the tables on the above referenced pages and submit an explanation, along with a formula, stating how the figures were calculated.

The requested explanation is enclosed in a cover letter from Dr. George Puritch of Eco-Care Technologies, Inc. to me. Eco-Care is Neudorff's North American research and development and marketing partner. In essence, Dr. Puritch states that the iron analyses were adjusted for the actual dry weight and averaged. However, the corrected values for samples 3, 4 and 5 were missing from the original tables, and the averages did not correspond to the non-corrected values. In order to correct this problem, Dr. Puritch has corrected the two tables on these pages by adding one row showing the dry weight correction value and one row showing the iron concentration based on the dry weight correction factor.

Please feel free to call me if you have any further questions.

Sincerely yours,



Walter G. Talarek

Enclosures

Eco-Care

Technologies Inc.

FAX

TO: Walt

FILE: M03-09, 3-13fx

FROM: George

DATE: March 13, 1997

Page 1 of 4

SUBJECT: Correction in Chemistry Vol 3 of 1165M

Thanks for your fax and the query from EPA. I have checked with the testing laboratory that did the analysis of the iron in the bait samples and studied the tables that we sent to EPA. The figures submitted to EPA are correct, however two rows were missing from the tables which should have been included to account for the final figures.

In the analysis, the iron is assessed on the dry weight of sample. This dry weight is assessed for each sample and compared to the starting weight. The analysis of iron is then corrected according to the actual dry weight compared to the original weight of the sample. With batches 1 and 2, the original weight and dry weight were the same so the correction was 1.00. However, with batches 3, 4 and 5 there were differences between the weights and suitable corrections were added. The iron concentration was adjusted for the actual dry weight and averaged. These were the figures stated for the average iron concentration. However, since the corrected values were missing from the table, the averages did not correspond to the non corrected values listed. This obviously caused confusion and I apologize for the mistake.

I have now corrected the two tables by adding one row showing the dry weight correction value and one row showing the iron concentration based on this dry weight correction value.

Since the values are the same there is no need for any further alterations.

Dry Weight Correction Formulas:

The dry weight correction value is obtained by weighing the original sample and then, after drying, weighing the final sample and dividing the final weight by the original weight and multiplying the result by 100.:

1. % SOLIDS

$$\frac{\text{Dry weight of sample}}{\text{Original weight of sample}} \times 100 = \% \text{ SOLIDS}$$

10555 West Saanich Road
Sidney, BC, Canada V8L 8L8

Telephone: 250-656-5555
Telefax: 250-656-5333

Eco-Care

March 13, 1997

Page 2/2

2. Correction Value

The dry weight correction value is obtained by dividing 100 by the % Solids:

$$100 \div \% \text{ SOLIDS} = \text{Dry Weight Correction Value}$$

The replicated iron concentration (mg/kg) is multiplied by the dry weight correction value to get the average iron concentration on a dry weight basis.

I trust that this is sufficient to explain the discrepancies, if not please do not hesitate to contact me.


Best wishes,

George

Note to file 67702-G (NEU1165M Slug and Snail Bait)
March 13, 1997

I talked to Walt Talarek, consultant for Neudorff, re: product chemistry review in work. The average iron concentration listed in Table 1b of "Volume 3: Product Chemistry, Analysis and Certification of Product Ingredients" (MRID 440427-01) for batches 3, 4 & 5 appears to be in error. The average iron concentrations as calculated by the BPPD chemist are consistently less than the concentrations listed in the table.

I told Mr. Talarek that the table must be corrected, or the numbers that exist must be justified. The certified limits listed on the CSF must be corrected based on the batch analyses or justified. I suggested that he send in replacement pages for the tables, rather than resubmitting the entire study. Mr. Talarek will discuss the matter with Neudorff, and send in any corrected pages, CSF, &/or justifications.



FIFRA

CONFIDENTIAL BUSINESS INFORMATION DOES NOT CONTAIN NATIONAL SECURITY INFORMATION (EO 12356)

Some information in the attached material may be entitled to treatment as trade secret or proprietary data section 7(d) and section 10 the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended.

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure while in his/her possession. Section 12(a)(2)(D) makes it unlawful for any employee to use to his/her own advantage or to reveal any confidential information (except to persons needing the information for the performance of official duties). A penalty of up to \$10,000 fine and up 3 years imprisonment may result from conviction of a violation on section 12(a)(2)(D).

Section 10(f) makes it a crime for any employee to disclose confidential information except as authorized by section 7 and 10 of FIFRA. A penalty of up to \$10,000 fine and up to one year in jail may result from conviction of a violation of section 10(f).

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CROSS REFERENCE PAGE

CROSS REFERENCE #1.

This cross reference number noted on a place-holder page is used in place of the following whole pages.

DELETED PAGES:

Found in this confidential attachment.

Pages	Reason for the Deletion	FIFRA References
5 - 7	Preliminary Analysis Certification of Limits	10(d) (1) (A) 10(d) (1) (A)

CB1

STUDY TITLE

NEU1165M

End-Use Product

EPA File Symbol

VOLUME 3

Product Chemistry
Analysis and Certification of Product Ingredients

DATA REQUIREMENTS

40 CFR 158.690
Guideline 151-13, -15, -16

CONFIDENTIAL ATTACHMENT

AUTHORS

David Almond
Catherine Stewart

STUDY COMPLETED ON

June 5, 1996

STUDY SUBMITTED BY

W. Neudorff GmbH KG
Postfach 1209
An der Mühle 3
D-31860 Emmerthal, Germany

STUDY PERFORMED BY

Eco-Care Technologies Inc.
10555 W. Saanich Rd.
Sidney, BC V8L 5L6 Canada

This document will publish in the
FEDERAL REGISTER of 11/22/77.
Approximately 24 hours after
publication, page numbers are
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Register Staff (FRS) at 202-260-2253.
Please refer to the FRL number at
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(NE Mall G-304).

Don A. Richards, Director
Federal Register Staff

Joan Karrie
CS #1, 7501W

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30427; FRL-5582-4]

Certain Companies; Applications to Register Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

*No comments Received
as of 3/4/97*

SUMMARY: This notice announces receipt of applications to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments must be submitted by (insert date 30 days after publication in the Federal Register).

ADDRESSES: By mail, submit written comments identified by the document control number [OPP-30427] and the file symbol to: Public Response and Program Resources Branch, Field Operations Divisions (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Environmental Protection Agency, Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will be accepted on disks in Wordperfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-30427]. No "Confidential Business Information" (CBI) should be submitted through e-mail. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submission can be found below in this document.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Joan Karrie, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. CS51B6, Westfield Building North

Tower, 2800 Crystal Drive, Arlington, VA 22202, (703) 308-8699; e-mail: karrie.joan@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

Products Containing Active Ingredients Not Included In Any Previously Registered Products

1. File Symbol: 67702-G. Applicant: W. Neudorff GmbH KG, Postfach 1209, an der Muhle 3, D-31860 Emmerthal, Germany. Product name: **NEU 1165M Slug and Snail Bait**. Molluscicide. Active ingredient: Iron phosphate at 1.0 percent. Proposed classification/Use: None. For on vegetables, fruits (including citrus), berries, outdoor ornamentals, greenhouses, and lawns.

2. File Symbol: 70061-R. Applicant: Themac Incorporation P.O. Box 5209, Valdosta, GA 31603-5209. Product name: Game Stop. Vertebrate repellent. Active ingredient: Fish oil at 11.6 percent. Proposed classification/Use: None. For use on foliage and twigs of trees, shrubs, and ornamental plants which are fed on by rabbits and deer.

Notice of approval or denial of an application to register a pesticide product will be announced in the **Federal Register**. The procedure for requesting data will be given in the **Federal Register** if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

A record has been established for this notice under docket number [OPP-30427] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this notice, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments

received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

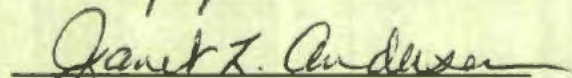
Written comments filed pursuant to this notice, will be available in the Public Response and Program Resources Branch, Field Operations Division at the address provided from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. It is suggested that persons interested in reviewing the application file, telephone this office at (703-305-5805), to ensure that the file is available on the date of intended visit.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

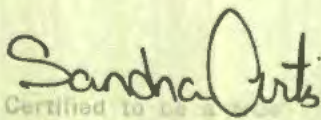
Dated: 1/6/97



Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 97-????? Filed ??-??-97; 8:45 am]

BILLING CODE 6560-50-F



Certified to be a
copy of the original.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

DEC 10 1996

W. NEUDORFF GMBH KG
C/O WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DR.
GREAT FALLS, VA 22066

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 12/06/96. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

441716- 00

W. Neudorff GmbH KG
c/o Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, VA 22066
USA

2. Regulatory action in support of which this package is submitted:

Submission of studies in support of application for registration of NEU 1165M Slug and Snail Bait, EPA File Symbol 67702-G.

3. Transmittal date:

December 5, 1996

4. List of studies submitted:

Volume 13 NEU 1165M: Acute Toxicity to the Ground
44171601 Beetle; Guideline 154-11

Volume 14 NEU 1165M: Acute Toxicity to the Rove Beetle;
44171602 Guideline 154-11

Volume 15 Acute Toxicity of NEU 1165M on Earthworms;
44171603 Guideline 154-11

Company Official:

Walter G. Talarek

Authorized Representative

Walter G. Talarek
Signature

Company Name:

W. Neudorff GmbH KG

Company Contact:

Walter G. Talarek

1008 Riva Ridge Dr. Phone
Great Falls, VA 22066

(703) 759-4837

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VIRGINIA 22066
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BPPD
12/2/96 JK

November 27, 1996

DELIVERED BY COURIER

Joan Karrie
Regulatory Action Leader, Team 90
Biopesticides and Pollution
Prevention Division (7501W)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Application to Register NEU 1165M Slug and Snail Bait; EPA File
Symbol 67702-G

Dear Ms. Karrie:

On June 10, 1996, W. Neudorff GmbH KG ("Neudorff") submitted an application for registration of its NEU 1165M Slug and Snail Bait product, EPA File Symbol 67702-G. In response, on October 24, 1996, Dr. Janet Andersen sent a letter to me stating in part that EPA had determined that some of the use patterns described on the product's label were food uses for which tolerances or exemptions from the requirement for a tolerance would be required. She also stated that EPA was requesting that applicants for registration needing tolerances refrain from submitting tolerance petitions until the procedures for processing these petitions in compliance with the new Food Quality Protection Act ("FQPA") have not been finalized. In the interim, she offered Neudorff the option of amending the product's label to eliminate these food uses and, therefore, the need for a tolerance or tolerance exemption. This would thereby allow EPA to continue the processing of the application while the issues related to implementation of the FQPA are being resolved.

By this letter and the attached, amended label (five copies), Neudorff is amending its application for registration to eliminate food uses and to retain the home and garden, ornamental plants, non-commercial

greenhouse and lawn uses. Neudorff hopes that these changes will allow EPA to proceed with the processing of its application for registration.

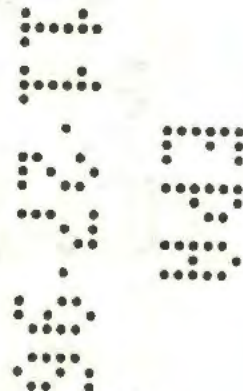
In closing let me thank you for your responsiveness on and assistance with some very difficult issues associated with this application. If you have any questions, please feel free to call me.

Sincerely yours,

Walt Talarek

Walter G. Talarek

Enclosures





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

248352

Application for Pesticide - Section I

1. Company/Product Number 67702-G	2. EPA Product Manager Andersen/90	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Slug and Snail Bait	PM# 90	
5. Name and Address of Applicant (Include ZIP Code) W. Neudorff GmbH KG c/o Walter G. Talarek, PC 1008 Riva Ridge Drive Great Falls, VA 22066 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to label deleting food uses, which eliminates the need for a tolerance or an exemption from the requirement for a tolerance.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
Certification must be submitted If "Yes" Unit Packaging wgt. No. per container If "Yes" Package wgt. No. per container				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Walter G. Talarek		Title Registration Agent		Telephone No. (Include Area Code) 703-758-4837	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Registration Agent			
4. Typed Name Walter G. Talarek		5. Date 11/27/96			

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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

NEU 1165M SLUG AND SNAIL BAIT

Active Ingredients:	By weight
Iron phosphate	1.0%
Inert Ingredients	99.0%
Total	100.0%

EPA registration #67702-

EPA establishment #67702-

NET WEIGHT LBS (kg)

CAUTION

KEEP OUT OF REACH OF CHILDREN

STATEMENT OF PRACTICAL TREATMENT

If in eyes, wash with large amounts of water.
Get medical attention if irritation persists.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

DISPOSAL: Do not reuse container. Securely wrap original container in several layers of newspaper and discard in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Avoid contact with eyes. In case of contact immediately flush eyes with plenty of water. Get medical attention if irritation persists.

Environmental Hazards: For terrestrial uses, do not apply directly to water, or areas where surface water is present or to intertidal areas below the mean high water mark.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Home And Garden

HOW TO APPLY: The slug bait granules should be scattered on the soil around or near the plants to be protected. Apply bait evenly at approximately 1 lb. per 1000 square feet (0.15 oz., or about 1 level tablespoon, per square yard) and reapply as the bait is consumed or at least every two weeks. Do not place in piles. If the ground is dry, wet it before applying bait. The soil should be moist but with little or no standing water.

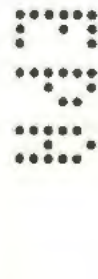
Reapply as the bait is consumed or at least every two weeks. Apply more heavily if the infestation is severe, if the area is heavily watered or after long periods of heavy rain. Apply only to the soil surface around plants, do not apply to foliage or other plant parts. See specific directions for different plant types and for inside greenhouses.

WHEN TO APPLY: Evening is the best time to apply the bait, as slugs and snails travel and feed mostly by night or early morning.

WHERE TO APPLY: All likely areas of infestation should be treated, especially around the perimeter of garden plots because these pests travel into plant areas from daytime refuges. They favor damp places around vegetable plants such as beans, tomatoes, lettuce, cabbage, celery and squash. Other favorite areas are flower gardens, rockeries, hedges, dichondra lawns, citrus groves, ivy patches, and other ground cover where they obtain shelter by day.

Vegetables

The bait can be used to protect any vegetables from slug and snail damage, including (but not limited to): artichokes, asparagus, beans, beets, blackeyed peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, corn, cucumbers, eggplants, garlic, lettuce, onions, peas, peppers, potatoes, radishes, rutabagas, spinach, squash, Swiss chard, tomatoes and turnips. Do not put the bait on plants. Scatter the bait around the perimeter of the vegetable plot at approximately 1 lb. per 1000 square feet to provide a protective "barrier" for slugs entering the garden plot. If slugs or snails are inside the rows, then scatter the bait on the soil around the base of the plants and between the rows.



Fruits Including Citrus

The bait can be used to protect non-commercial fruits from slugs and snails, including (but not limited to): apples, avocados, apricots, cherries, grapes, melons, peaches, plums, citrus, pears. For seedlings spread the bait around the base of the stem, without touching the plant. Apply at 0.15 oz., or 1 level tablespoon, per square yard, in a 6 inch circular band around the base of the plants to be protected. For older trees, spread the bait around the base of the tree to intercept slugs and snails traveling to the trunk. Apply the bait at approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders.

Berries

The bait can be used to protect non-commercial berries from slugs and snails, including (but not limited to): strawberries, blackberries, blueberries, boysenberries, loganberries, raspberries. Do not apply the baits on the plants. Spread the bait around the perimeter of the plot to intercept slugs and snails migrating toward the berries. Use a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders. If slugs and snails are already in the plots, then carefully spread bait between the furrows near the base of the plants. For small plots, treat around the base of the plants to be protected. Do not spread over the entire area but apply selectively.

Outdoor Ornamentals

Scatter bait in a 6 inch circular band around the base of the plants to be protected at 0.15 oz., or 1 level tablespoon, per square yard. If plants are next to a grassy area, spread the bait between the ornamentals and the grass. Slugs traveling to the plants will encounter the bait before reaching the plant. Scatter the bait around the perimeter of the plot at approximately 1 lb. per 1000 square feet to intercept snails and slugs traveling to the plot.

Greenhouses

Where snails are a problem in non-commercial greenhouses, scatter the bait in the plant pots of plants being damaged or around pots on greenhouse benches. Apply about ½ teaspoon per 9 inch pot. Do not put the bait on the plant.

Lawns

The bait can be used to protect lawns. When slugs or snails are detected, scatter the bait at a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with a granular spreader where the slugs or snails are observed.

WARRANTY

Seller warrants that this product conforms to the chemical description on this label and is reasonably fit for purposes stated on this label only when used in accordance with directions under normal use conditions. This warranty does not extend to use of this product contrary to label directions, or under abnormal use conditions, or under conditions not reasonably foreseeable to seller. Buyer assumes all risk of any such use. Seller makes no other warranties, either expressed or implied.

Marketing claims and product information that may be presented on the container or supplemental wording:

- NOTE: This package is sold by weight. Contents may have settled during shipment.
- The highly compressed granules (pellets) are easy to use, clean to handle and economical.
- So unique it is (its) patented. US Patent number 5,437,870.
- (New) patented technology. (New) patented snail & (and) slug killer. Unique, patented formula.
- Easy-to-use (ready-to-use) (RTU) granular (pellet) formulation.
- Kills snails & (and) slugs.
- Treats (will treat) x,xxx sq. ft.
- Will bait (up to) x,xxx square feet.
- Remains effective after rain or sprinkling. Not affected by rain.
- Proven snail & (and) slug killer (kill, control).
- Convenient. Easy-to-use. Requires no mixing, spraying, or special applicators. Just scatter lightly on the soil surface in infested areas.
- Reliable. Use with confidence. Effective. Your first line of defense. Effective pest control.
- This container is made from XX% recycled materials.
- Maximum snail & slug control . . . GUARANTEED. See back panel.
- SATISFACTION GUARANTEED. See back panel.
- You've tried the rest, this time try the best.
- This time try the best.
- Ideal for vegetable gardens. Can be used in vegetable gardens.
- For use around vegetables, fruit and citrus trees, berries, ornamentals, shrubs, flowers, trees, lawns, gardens, and in greenhouses.

GENERAL INFORMATION (WHY SLUG AND SNAIL BAIT IS SO EFFECTIVE)

This product is a unique blend of an iron phosphate active ingredient, originating from soil, with slug and snail bait additives. It is used as an ingredient in fertilizers. The bait which is not ingested by snails and slugs will degrade and become part of the soil in your garden.

The bait is extremely (highly) attractive to slugs and snails and lures them from their hiding places and plants. Ingestion, even in small amounts, will cause them to cease feeding. This physiological effect of the bait gives immediate protection to the plants even though the slugs and snails may remain in the area. After eating the bait, the slugs and snails cease feeding, become less mobile and begin to die within three to six days. Dead slugs and snails may not be visible as they often crawl away to secluded places to die. Plant protection will be observed in the dramatic decrease in plant damage.

This product is effective against a wide variety of slugs and snails and will give protection to lawns, gardens, greenhouses, outdoor ornamentals, vegetable gardens, fruits, berries, citrus and crop plants. The bait can be scattered on the lawn or on the soil around any vegetable plants, flowers or fruit trees or bushes to be protected

Slug and Snail Information

Slugs and snails controlled by this product include (but are not limited to): *Deroceras reticulatum* (Field slug), *Deroceras laeve* (Smooth slug), *Arion subfuscus* (Dusky slug), *Arion circumscriptus* (Gray garden slug), *Arion hortensis* (Black field slug), *Arion rufus* (Large red slug), *Arion ater* (Large black slug), *Limax flavus* (Spotted garden slug), *Limax tenellus* (Slender slug), *Arion limax columbianus* (Banana slug), *Helix* spp., spp., *Helicella* spp., and *Cepaea* spp.

Slugs and snails are related molluscs and are some of our most destructive garden pests. They appear quite different from each other because snails have a shell and slugs do not. Mature slugs and snails lay eggs in clumps in the soil, under stones, or under garden debris. The eggs generally hatch after one month of favorable weather conditions. As soon as the eggs hatch the tiny molluscs begin feeding. Even small slugs and snails can cause significant plant damage.

As they grow, slugs and snails feed on vegetation and migrate toward areas of more food and shelter. They feed during the cool of the evening, night or early morning. They leave a shiny, mucous trail as evidence of their presence. In cool weather slug and snail feeding damage increases. During hot ~~dry~~ weather slugs will hide, seeking shelter in damp, cool places.

Because they migrate it is very difficult, if not impossible, to completely eliminate slugs and snails as garden pests. However, with a consistent program using Slug and Snail Bait, their numbers can be reduced to where they are no longer a problem for your plants.

Registrant: W. Neudorff GmbH KG, Postfach 1209, an der Mühle 3,

SLUG AND SNAIL BAIT LABEL
Page 6/6

D-31860 Emmerthal, Germany

United States Patent #5,437,870
File: Register\Slug\Label1 April 11, 1998



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NOV 19 1996
BPPD

11/17/96 JK

November 12, 1996

Janet L. Andersen, Ph.D.
Director, Biopesticides and Pollution
Prevention Division (7501W)
Office of Pesticide Programs
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460-0001

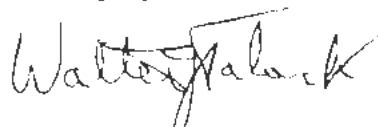
Re: NEU 1165M Slug and Snail Bait
EPA File Symbol 67702-G
Application for Registration Dated 6/10/96

Dear Dr. Andersen:

I am forwarding copies of revised "Data Requirements Listings for New Biochemical Active Ingredients" for the generic and product-specific data applicable to W. Neudorff GmbH KG's ("Neudorff's") NEU 1165M Slug and Snail Bait product, EPA File Symbol 67702-G. These revised listings incorporate the MRID numbers that were recently assigned by EPA to the studies submitted by Neudorff in support of its application for registration of this product.

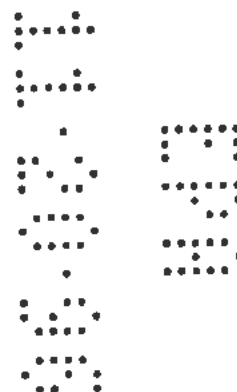
Please feel free to call me if you have any questions.

Sincerely yours,



Walter G. Talarek

Enclosures



EPA

11-20-96

Revised 11/12/96

PRODUCT-SPECIFIC DATA
DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

1. PRODUCT NAME <u>NEU 1165M</u>		2. EPA REG. NO/FILE SYMBOL <u>67702-</u>		3. FORMULATORS EXEMPTION SELECTED YES _____ NO <u>X</u>		4. PAGE <u>1</u> of <u>6</u>	
5. APPLICANT'S NAME & ADDRESS W. Neudorff GmbH KG An der Muhle 3 D-31860 Emmerthal Germany		6. APPLICATION FOR REGISTRATION DATED <u>6/10/96</u>		7. NAME OF ACTIVE INGREDIENT(S): Iron phosphate			
8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT					
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or Offer to Pay (OTP) Enclosed. Indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)
158.690(a)	PRODUCT ANALYSIS DATA						
151-10	Identity of Ingredients	X	6/10/96				44 07 06 01
151-11	Manufacturing Process	X	6/10/96				44 07 06 01
151-12	Discussion of Formation of Unintentional Ingredients	X	6/10/96				44 07 06 01
151-13	Analysis of Samples	X	6/10/96				44 04 27 01
151-15	Certification of Limits	X	6/10/96				44 042 70 1
151-16	Analytical Methods	X	6/10/96				44 042 70 1
151-17	Color	X	6/10/96				4 40 42 70 2
151-17	Physical State	X	6/10/96				4 40 42 702
151-17	Order	X	6/10/96				4 40 42 702

EPA

PRODUCT-SPECIFIC DATA

DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

 11-29-96
 PAGE 2 of 6

1. PRODUCT NAME NEU 1165M		2. EPA REG. NO/FILE SYMBOL 67702-		3. FORMULATORS EXEMPTION SELECTED YES _____ NO <u>X</u>		4. NAME OF ACTIVE INGREDIENT(S): Iron phosphate	
5. APPLICANT'S NAME & ADDRESS W. Neudorff GmbH KG An der Muhle 3 D-31860 Emmerthal Germany		6. APPLICATION FOR REGISTRATION DATED 6/10/96					
8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT					
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or offer to Pay (OTP) Enclosed. Indicate "p" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)
151-17	Melting Point						N.A.
151-17	Boiling Point						N.A.
151-17	Density	X	6/10/96				
151-17	Solubility						N.A.
151-17	Vapor Pressure						N.A.
151-17	Dissociation Constant						N.A.
151-17	Octanol/Water Partitioning Coefficient						N.A.
151-17	pH	X	6/10/96				
151-17	Stability	X	6/10/96				
151-17	Oxidizing/Reducing Action						N.A.

Revised 11/12/96
PRODUCT-SPECIFIC DATA

DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

EPA

11.00.96

1. PRODUCT NAME NEU 1165M		2. EPA REG. NO/FILE SYMBOL 67702-		3. FORMULATORS EXEMPTION SELECTED YES _____ NO <input checked="" type="checkbox"/>		4. PAGE <u>3</u> of <u>6</u>	
5. APPLICANT'S NAME & ADDRESS W. Neudorff GmbH KG An der Muhle3 D-31860 Emmerthal Germany		6. APPLICATION FOR REGISTRATION DATED 6/10/96		7. NAME OF ACTIVE INGREDIENT(S): Iron phosphate			
8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT					
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or Offer to Pay (OTP) Enclosed. Indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)
151-17	Flammability						N.A.
151-17	Explodeability						N.A.
151-17	Storage Stability	X	6/10/96				
151-17	Viscosity						N.A.
151-17	Miscibility						N.A.
151-17	Corrosion Characteristics	X	6/10/96				
151-17	Dielectric Breakdown Voltage						N.A.
151-10	Submittal of Samples	TO BE SUBMITTED WHEN ASKED BY PRODUCT MANAGER					

EPA

11-20-96

Revised 11/12/96
PRODUCT-SPECIFIC DATA
DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

1. PREVIOUS NAME NEU 1165M		2. EPA REG. NO/FILE SYMBOL 67702-		3. FORMULATORS EXEMPTION SELECTED YES _____ NO <u>X</u>		4. PAGE <u>4</u> of <u>6</u>	
5. APPLICANT'S NAME & ADDRESS W. Neudorff GmbH KG An der Muhle 3 D-31860 Emmerthal Germany		6. APPLICATION FOR REGISTRATION DATED 6/10/96		7. NAME OF ACTIVE INGREDIENT(S): Iron phosphate			
8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT					
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or Offer to Pay (OTP) Enclosed. Indicate "pp" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)
§158.680(c)	TOXICOLOGY						
152-10	Acute Oral LD ₅₀ , Rat	X	6/10/96				44 04 27 04
152-11	Acute Dermal LD ₅₀	X	6/10/96				44 04 27 05
152-12	Acute Inhalation LD ₅₀ , Rat						Waiver Request
152-13	Primary Eye Irritation, Rabbit	X	6/10/96				44 04 27 06
152-14	Primary Dermal Irritation	X	6/10/96				44 04 27 07
152-15	Hypersensitivity Studies						Waiver Request
152-16	Hypersensitivity Incidents						N.A.
152-17	Studies to Detect Genotoxicity						N.A.
152-20	90 Day feeding						N.A.

Revised 11/12/96
PRODUCT-SPECIFIC DATA

DATA REQUIREMENT LISTING FOR NEW BIOCHEMICAL ACTIVE INGREDIENTS

EPH

11.20.05

1. PRODUCT NAME NEU 1165M		2. EPA REG. NO/FILE SYMBOL 67702-		3. FORMULATORS EXEMPTION SELECTED YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		4. PAGE 5 of 6		
5. APPLICANT'S NAME & ADDRESS W. Neudorff GmbH KG An der Muhle 3 D-31860 Emmerthal Germany		6. APPLICATION FOR REGISTRATION DATED 6/10/96		7. NAME OF ACTIVE INGREDIENT(S): Iron phosphate				
8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or Offer to Pay (OTP) Enclosed. Indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	NRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
152-21	Teratogenicity						N.A.	
§158.690(b)	RESIDUE CHEMISTRY							
153-3	Chemical Identity						Waiver Request	
153-3	Directions for Use						Waiver Request	
153-3	Nature of the Residue, Plants						Waiver Request	
153-3	Proposed Tolerance (Exemption)						Waiver? Request	
153-3	Reasonable Ground in Support of Petition						Waiver Request	

EPN

4. PAGE 6 of 9

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NEU 1165M SLUG AND SNAIL BAIT

Active Ingredients:	By weight
Iron phosphate	1.0%
Inert Ingredients	99.0%
Total	100.0%

EPA registration #67702-

EPA establishment #67702-

NET WEIGHT LBS (kg)

CAUTION

KEEP OUT OF REACH OF CHILDREN

STATEMENT OF PRACTICAL TREATMENT

If in eyes, wash with large amounts of water.
Get medical attention if irritation persists.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

DISPOSAL: Do not reuse container. Securely wrap original container in several layers of newspaper and discard in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Avoid contact with eyes. In case of contact immediately flush eyes with plenty of water. Get medical attention if irritation persists.

Environmental Hazards: For terrestrial uses, do not apply directly to water or areas where surface water is present or to intertidal areas below the mean high water mark.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Home And Garden

HOW TO APPLY: The slug bait granules should be scattered on the soil around or near the plants to be protected. Apply bait evenly at approximately 1 lb. per 1000 square feet (0.15 oz., or about 1 level tablespoon, per square yard) and reapply as the bait is consumed or at least every two weeks. Do not place in piles. If the ground is dry, wet it before applying bait. The soil should be moist but with little or no standing water.

Reapply as the bait is consumed or at least every two weeks. Apply more heavily if the infestation is severe, if the area is heavily watered or after long periods of heavy rain. Apply only to the soil surface around plants, do not apply to foliage or other plant parts. See specific directions for different plant types and for inside greenhouses.

WHEN TO APPLY: Evening is the best time to apply the bait, as slugs and snails travel and feed mostly by night or early morning.

WHERE TO APPLY: All likely areas of infestation should be treated, especially around the perimeter of garden plots because these pests travel into plant areas from daytime refuges. *pests* → They favor damp places around vegetable plants such as beans, tomatoes, lettuce, cabbage, celery and squash. Other favorite areas are flower gardens, rockeries, hedges, dichondra lawns, citrus groves, ivy patches, and other ground cover where they obtain shelter by day.

Vegetables

non-food use →
The bait can be used to protect any vegetables from slug and snail damage, including (but not limited to): artichokes, asparagus, beans, beets, blackeyed peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, corn, cucumbers, eggplants, garlic, lettuce, onions, peas, peppers, potatoes, radishes, rutabagas, spinach, squash, Swiss chard, tomatoes and turnips. Do not put the bait on plants. Scatter the bait around the perimeter of the vegetable plot at approximately 1 lb. per 1000 square feet to provide a protective "barrier" for slugs entering the garden plot. If slugs or snails are inside the rows, then scatter the bait on the soil around the base of the plants and between the rows.



Fruits Including Citrus

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Berries

The bait can be used to protect non-commercial berries from slugs and snails, including (but not limited to): strawberries, blackberries, blueberries, boysenberries, loganberries, raspberries. Do not apply the baits on the plants. Spread the bait around the perimeter of the plot to intercept slugs and snails migrating toward the berries. Use a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders. If slugs and snails are already in the plots, then carefully spread bait between the furrows near the base of the plants. For small plots, treat around the base of the plants to be protected. Do not spread over the entire area but apply selectively.

Outdoor Ornamentals

Scatter bait in a 6 inch circular band around the base of the plants to be protected at 0.15 oz., or 1 level tablespoon, per square yard. If plants are next to a grassy area, spread the bait between the ornamentals and the grass. Slugs traveling to the plants will encounter the bait before reaching the plant. Scatter the bait around the perimeter of the plot at approximately 1 lb. per 1000 square feet to intercept snails and slugs traveling to the plot.

Greenhouses

Where snails are a problem in non-commercial greenhouses, scatter the bait in the plant pots of plants being damaged or around pots on greenhouse benches. Apply about ¼ teaspoon per 9 inch pot. Do not put the bait on the plant.

Lawns

The bait can be used to protect lawns. When slugs or snails are detected, scatter the bait at a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with a granular spreader where the slugs or snails are observed.

WARRANTY

Seller warrants that this product conforms to the chemical description on this label and is reasonably fit for purposes stated on this label only when used in accordance with directions under normal use conditions. This warranty does not extend to use of this product contrary to label directions, or under abnormal use conditions, or under conditions not reasonably foreseeable to seller. Buyer assumes all risk of any such use. Seller makes no other warranties, either expressed or implied.

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-The highly compressed granules (pellets) are easy to use, clean to handle and economical.

-So unique it is (its) patented. US Patent number 5,437,870.

(New) patented technology. (New) patented snail & (and) slug killer. Unique, patented formula.

-Easy-to-use (ready-to-use) (RTU) granular (pellet) formulation.

-Kills snails & (and) slugs.

-Treats (will treat) x,xxx sq. ft.

-Will bait (up to) x,xxx square feet.

-Remains effective after rain or sprinkling. Not affected by rain.

-Proven snail & (and) slug killer (kill, control).

-Convenient. Easy-to-use. Requires no mixing, spraying, or special applicators. Just scatter lightly on the soil surface in infested areas.

-Reliable. Use with confidence. Effective. Your first line of defense. Effective pest control.

-This container is made from XX% recycled materials.

-Maximum snail & slug control . . . GUARANTEED. See back panel.

-SATISFACTION GUARANTEED. See back panel.

-You've tried the rest, this time try the best.

-This time try the best.

-Ideal for vegetable gardens. Can be used in vegetable gardens.

-For use around vegetables, fruit and citrus trees, berries, ornamentals, shrubs, flowers, trees, lawns, gardens, and in greenhouses.

GENERAL INFORMATION (WHY SLUG AND SNAIL BAIT IS SO EFFECTIVE)

This product is a unique blend of an iron phosphate active ingredient, originating from soil, with slug and snail bait additives. It is used as an ingredient in fertilizers. The bait which is not ingested by snails and slugs will degrade and become part of the soil in your garden.

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This product is effective against a wide variety of slugs and snails and will give protection to lawns, gardens, greenhouses, outdoor ornamentals, vegetable gardens, fruits, berries, citrus and crop plants. The bait can be scattered on the lawn or on the soil around any vegetable plants, flowers or fruit trees or bushes to be protected

Slug and Snail Information

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As they grow, slugs and snails feed on vegetation and migrate toward areas of more food and shelter. They feed during the cool of the evening, night or early morning. They leave a shiny, mucous trail as evidence of their presence. In cool weather slug and snail feeding damage increases. During hot or cold weather slugs will hide, seeking shelter in damp, cool places.

Because they migrate it is very difficult, if not impossible, to completely eliminate slugs and snails as garden pests. However, with a consistent program using Slug and Snail Bait, their numbers can be reduced to where they are no longer a problem for your plants.

Registrant: W. Neudorff GmbH KG, Postfach 1209, an der Mühle 3,

D-31860 Emmerthal, Germany

United States Patent #5,437,870
File: RegistraSlugLabel1 April 11, 1996



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October 3, 1996

CV 617
BPPD
11-8-96
JK

DELIVERED BY COURIER

Joan Karrie
Regulatory Action Leader, Team 90
Biopesticides and Pollution
Prevention Division (7501W)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Application to Register NEU 1165M Slug & Snail Bait; EPA File
Symbol 67702-G

Dear Ms. Karrie:

With this letter, I am forwarding the documents that we discussed over the telephone yesterday and today.

First, you will find a copy of EPA's September 28, 1994, Federal Register notice listing minimal risk inerts and stating that substances commonly consumed as food will be considered acceptable for use in all pesticide products, both food and non-food use, and will not require a specific exemption from tolerance.

Second, you will find copies of two labels for metaldehyde slug and snail bait products which allow their use on various food crops, including strawberries, blueberries, beans, lettuce and potatoes. Although there is an EPA tolerance for strawberries, there do not appear to be any tolerances for these other crops.

Third, you will find a series of EPA documents relating to Lonza's request that metaldehyde used in slug and snail baits around food crops be considered a non-food use. The basis for this request was that metaldehyde and its degradates do not translocate from soil into plant tissues and, therefore, do not represent a food use. (However, EPA did find that there was translocation and denied Lonza's request.) These documents also indicate that the current metaldehyde tolerance for strawberries is inappropriate and should be revoked.

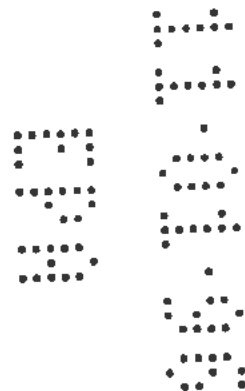
If you have any questions, please feel free to call me.

Sincerely yours,

Walter Talarek

Walter G. Talarek

Enclosures



formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label and the list of data references used to support registration are available for public inspection in the office of the Product Manager listed above. The data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 1132, Crystal Mall Bldg. #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703-305-5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., S.W., Washington, DC 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Production, registration.

Dated: September 9, 1994.

Stephen L. Johnson,
Director, Registration Division, Office of
Pesticide Programs

[FR Doc. 94-23807 Filed 9-27-94; 8:45 am]
BILLING CODE 5500-80-F

[OPP-361-08; FRL-4672-5]

Inert Ingredients in Pesticide Products; List of Minimal Risk Inerts

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is issuing a list of inert ingredients considered to be of minimal risk in pesticide products (List 4A). In addition, EPA is announcing that substances commonly consumed as food will also be considered minimal risk, List 4A, even if they have previously not been used in pesticide products and are therefore not currently on the list. Substances commonly consumed as foods will be considered acceptable for use in all pesticide products, both food and nonfood use, and will not require a specific exemption from tolerance. **EFFECTIVE DATE:** September 28, 1994.

ADDRESSES: By mail, submit written comments identified by the document control number [OPP-36140B] to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460. In person, deliver comments to: Rm. 1132, Crystal Mall Bldg. #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part of all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Tina Levine, Registration Support Branch, Registration Division (7503W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, Arlington, VA 22202, (703)-308-8393.

SUPPLEMENTARY INFORMATION: EPA announced its policy on toxic inert ingredients in pesticide products in the Federal Register of April 22, 1987 (52 FR 13305). Through this policy, EPA encourages the use of the least toxic inert ingredients available and requires the development of data necessary to determine the conditions of safe use of products that contain toxic inert ingredients. In developing this policy, EPA categorized inert ingredients into the following four lists according to toxicity:

List 1—Inerts of toxicological concern.

List 2—Potentially toxic inerts, with high priority for testing.

List 3—Inerts of unknown toxicity.

List 4—Inerts of minimal concern.

In the Federal Register of November 22, 1989 (54 FR 48314), EPA issued a notice announcing some modifications to the previously published Lists 1 and 2. In that notice, EPA also noted that List 4 was being divided into two parts. The original List 4 became List 4A, representing minimal risk inert ingredients. List 4B was created to represent inert ingredients for which

EPA has sufficient information to conclude that their current use patterns in pesticide products will not adversely affect public health and the environment. List 4B will be developed as EPA works through the inerts strategy and reviews the current inerts on Lists 2 and 3.

EPA is issuing List 4A to provide guidance to formulators of active ingredients being proposed for deregulation under section 25(b) of the Federal Insecticide, Fungicide and Rodenticide Act. The substances included on List 4A can be added to such active ingredients without jeopardizing their deregulated status. These minimum risk inert ingredients are recognized as safe for use in pesticide products based upon their known properties.

In reviewing List 4 inert ingredients for the proposed section 25(b) rule, many inerts on the original List 4 were moved from List 4A to List 4B. In particular, acutely toxic inerts were moved to 4B because, although the testing of products for acute toxicity ensures low concern for these inerts in registered products, without such regulatory oversight there may be unacceptable acute risks. In addition, many of the inerts on the original List 4 received little review for environmental fate and ecological effects. Those inerts have been moved to List 4B while EPA further assesses their environmental risks. EPA also plans soon to move inert ingredients now on List 3 to Lists 4A and 4B. The Food and Drug Administration has considered these inerts for use as direct food additives and in pharmaceuticals, and they are undergoing additional review by the FDA and the Office of Water before final disposition.

Many of the inerts on List 4A are commonly consumed foods. There may be other foods useful as inert ingredients in pesticide products that are not included in this list because they have not been used in pesticide products up to now. EPA is announcing a policy that, as a general matter, it will consider all commonly consumed foods as List 4A, inerts of minimal concern. Although some commonly consumed foods are currently exempted from the requirement of a tolerance by virtue of their listing in the 40 CFR 180.1001, EPA generally will no longer list common foods in this way. EPA generally considers substances that are commonly consumed as food to fall into the category of "generally recognized as safe" substances. EPA will not require a specific listing for commonly consumed foods in this subpart unless specific information suggests that categorization

Tip for
USE AROUND
CHILDREN
& PETS

LILLY/MILLER

SLUG AND SNAIL BAIT

PROTECTS
VEGETABLES
& FLOWERS

NET WEIGHT 3 LBS. (1.3 kg)

ACTIVE INGREDIENT
Metaldehyde (2,4,6-trimethyl-3,5,7-
trinitrophenol) 2.0%

INERT INGREDIENTS 98.0%

Keep out of reach of children

CAUTION

This material is extremely poisonous. If swallowed, it may be fatal. If inhaled, it may be fatal. If it gets on your skin, wash it off immediately. If it gets on your clothes, wash them separately. Do not use near food or feedstuffs.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful if swallowed. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Wash thoroughly after use. Keep out of reach of children and domestic animals. Avoid contamination of feed and foodstuffs.

IMPORTANT: Keep away from children, dogs and other pets. Bait may be attractive to dogs. Confine pets during application to prevent them from believing they are being fed. Use and store under conditions where there will not be a hazard.

STATEMENT OF PRACTICAL TREATMENT

If inhaled: Remove to fresh air. If swallowed: Person is not breathing give artificial respiration. Preferably mouth-to-mouth. Get medical attention. If in eyes: Flush eyes with plenty of water. Get medical attention. If on skin: Wash with plenty of water. Soap and water.

ENVIRONMENT

Do not apply directly to water. Do not contaminate water. Do not dispose of equipment, washwater, or other material in water. Do not feed to dogs or other domestic animals.

DIRECTIONS FOR USE

This is a violation of Federal law to use this product in a manner inconsistent with its labeling. For household use only.

STORAGE AND DISPOSAL

Store this product in its original container and keep in a locked storage area out of reach of children and domestic animals. Do not reuse container. Securely wrap original container in several layers of newspaper and discard in trash.

SLUG AND SNAIL BAIT is a ready-to-use bait which attracts and kills slugs and snails. Remains effective after rainfall or sprinkling. Protects ornamentals, flowers, fruits and vegetables from slug and snail damage.

THE CHAS. H. LILLY CO.
200 FARM ROAD, CHAS. H. LILLY CO.

These pests are mainly night feeders and their presence can be detected by a shiny, mucous trail. They hide during the day in damp, protected areas such as rockeries, flower beds, shrubs, hedges and in the following ground covers.

For best results, bait areas to be treated. Water and damp. Apply bait in the afternoon or evening hours since these pests feed mainly at night.

Brush the bait into the infested area using a brush or 1750.

Repeat application at two week intervals during periods of damp weather, or during heavy infestations.

When invasion from adjacent areas is likely, apply a band of SLUG AND SNAIL BAIT along the entire length of the infested area to provide a barrier and good control.

Removal of loose boards, bricks, plant debris or other material which may offer shelter to slugs and snails will add to the effectiveness of control.

FRUITS AND VEGETABLES: To control slugs and snails around the following fruits and vegetables, lightly broadcast around the plants. Do not contaminate edible parts.

Fruits: Apples, Blackberries, Blueberries, Cherries, Citrus, Grapes, Melons, Peaches, Pears, Strawberries.

Vegetables: Asparagus, Beans, Beans, Broccoli, Cabbage, Carrots, Cauliflower, Corn, Cucumbers, Eggplants, Garlic, Lettuce, Onions, Potatoes, Peas, Peppers, Potatoes, Radishes, Rutabagas, Spinach, Squash, Swiss Chard, Tomatoes and Turnips.

WARRANTY: The use of this material being subject to conditions beyond our knowledge and control, the seller makes no warranty of any kind, expressed or implied, concerning the effects of this product when not used in accordance with directions.

Filled by weight not by volume. Product may settle after packaging.

EPA REG. NO. 002-343
EPA REG. NO. 002-343
EPA REG. NO. 002-343

Tips For Use Around Pets & Children

In backyards and gardens there is a concern about protecting children, pets and wildlife from coming into contact with slug baits. These are suggestions of ways to reduce the likelihood of exposure. However, all slug baits containing metaldehyde can be harmful and it may not be possible to avoid children, pets or wildlife are able to come in contact with the bait.

The first way to protect children, pets and wildlife is to keep the bait over the infested area. Follow the label directions. A second way to protect children, pets and wildlife is to use an effective method of bait application. A big pile of bait is more attractive to children, pets and wildlife.

Placing the bait in a purchased or home made trap is another way to provide some protection. Follow the directions on store-bought traps. Bait the trap and place them.

Home made traps can be made by cutting a hole in the sides of empty margarine or yogurt containers and replacing the lids.

Place a small amount of bait in the trap. Secure the trap in its location by tying it to a stake, partially burying it, putting a rock on it, or other such method.

Place the trap in moist, protected spots, in areas of heavy shade, under shrubs, at the edges of dense ground covers, etc. Place traps out of the way of curious children or animals.

Check the traps each day and throw away the slugs you have caught.

Slug baits may not drop snails and slugs in their tracks. They may crawl away a bit to die. But, if the trap is not catching any slugs, try another location.

Please use all pest control products carefully.

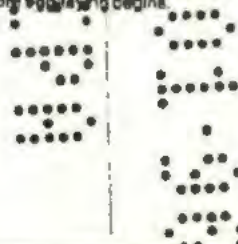
ABOUT SLUGS AND SNAILS

Slugs and snails are voracious feeders on the more succulent part of plants especially young seedlings, vegetables, or ornamentals and flowers. Slugs are mollusks which lack the external shell as found on the snail.

Slugs and snails feed mainly at night or on damp dark days. They prefer mild moist conditions and usually hide during cold or dry, hot weather.

Slugs and snails lay their eggs singly or in clusters under plant debris, rocks or in the soil. They reproduce almost continuously during mild, moist weather. The eggs usually hatch in about 14 to 28 days. These tiny slugs grow slowly and begin feeding immediately upon hatching.

For best control of these pests, baiting should be practiced year around especially in early fall before the winter rains so as to kill slugs before they begin to feed.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 14 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Response to the Metaldehyde Reregistration
Standard: Residue Data (MRID # 42092701,
CBRS # 9200, Barcode No. D172616)

FROM: R. B. Perfetti, Ph.D., Chemist
Reregistration Section
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: E. Zager, Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: E. Saito, Acting Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

and

L. Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division (H7508W)

Attached is a review of a metaldehyde metabolism study submitted by Lonza Inc. response to the metaldehyde Reregistration Standard. This information was reviewed by Acurex Corporation under supervision of CBRS, HED.

This document has undergone secondary review in CBRS and has been revised to reflect the Branch policies.

Please see our conclusions in the attachment regarding the adequacy of the information provided by the Registrant. Also see the conclusions of the HED Metabolism Committee regarding residues of metaldehyde.

A Tentative Residue Chemistry Data Summary Table is also included at the end of this review.



If you need additional input please advise.

Attachment 1 : Review of Metaldehyde Plant Metabolism Data.

cc: With Attachment 1: R. B. Perfetti, Metaldehyde Reregistration
Standard File, Metaldehyde Subject File, Acurex and Circ..

cc: Without Attachment: RF.

2025

METALDEHYDE
(Chemical Code 053001)
(CBRS No. 9200; DP Barcode D172616)

TASK 3

**Registrant's Response
to Residue Chemistry Data
Requirements**

May 14, 1992

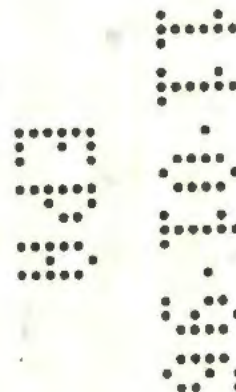
Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Environmental Corporation
Eastern Region Operations
4915 Prospectus Drive
P.O. Box 13109
Research Triangle Park, NC 27709



METALDEHYDE

(Chemical Code 053001)

(CBRS No. 9200; DP Barcode D172616)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

Task-3

BACKGROUND

Metaldehyde is a molluscicide registered for use on numerous food/feed sites including orchard fruits and nuts, small fruits and berries, vegetables, alfalfa, and clover.

A food additive regulation is in effect for dust-treated strawberries in which a tolerance of "zero" is specified, expressed in terms of metaldehyde per se (40 CFR §185.4025[b]). This food additive tolerance is inappropriate and should be revoked. Prior to the Pesticide Assessment Guidelines issued in 10/82, 408 tolerances had generally not been required for food/feed uses of baits, such as metaldehyde. However, Pesticide Assessment Guidelines, Subdivision O states that if residues could occur in food or feed, the use is considered to be a food use and a petition for tolerance/exemption from tolerance is required. The Metaldehyde Guidance Document dated 12/88 stated that the Agency had no basis for concluding that residues will not occur in or on food and feed crops treated with metaldehyde. The Guidance Document required plant metabolism studies on three dissimilar crops.

The 1988 Residue Chemistry Chapter provides a discussion of metabolism studies with bean and strawberry leaves. Strawberry leaves at 1 or 2 days following [¹⁴C]metaldehyde foliar application showed approximately 20-30% of the recovered radioactivity in trapped volatiles and 53-54% as chloroform-soluble residues. ¹⁴C-Residues recovered from bean leaves 4 days after treatment included 36% trapped volatiles and 25% chloroform-solubles. The registrant reported that unchanged parent compound was the predominant residue in the chloroform extracts.

In response to the Guidance Document requirement for plant metabolism data, Lonza, Inc. met with the Agency on 5/2/89 to discuss data requirements. In a Lonza letter of 5/17/89 summarizing that meeting, it was stated that the Agency would consider metaldehyde a non-food use if the registrant could demonstrate that metaldehyde did not translocate to plants. Subsequently, Lonza (10/89; no MRID assigned) submitted a protocol for metabolism studies with strawberries and citrus. The Agency concluded that a study conducted according to the submitted protocol would not yield sufficient data to determine whether or not metaldehyde use on or around food crops could be considered a non-food use (R. Perfield, CBRS No. 6322 dated 4/18/90). The review cited the following deficiencies in the protocol: (i) the study would be limited to strawberries and citrus and, thus, would not be representative of all registered crops; (ii) the data would be representative only of granular (G) and pelleted/tableted (P/T) formulations, and would not depict the potential for uptake of a soil-

applied EC formulation; and (iii) the registrant proposed to report nondetectable residues as "zero." The Agency recommended tests on strawberries, citrus, and a leafy vegetable using a G or P/T formulation and in separate tests, an EC formulation.

Lonza, Inc. (1991; MRID 42092701) submitted data from a soil application study of [^{14}C]metaldehyde on strawberries. In their transmittal letter, the registrant referred to their meeting with the Agency and noted that the Agency had recommended eliminating foliar uses. The Agency had also stated a need to demonstrate that metaldehyde nor its primary degradates, paraldehyde and acetaldehyde, do not translocate from soil or air into plant tissues. The Agency recommended that very sensitive analytical methodology and/or radioactive metaldehyde be used to detect residues at 0.01 ppm. The data from the strawberry study are reviewed here for adequacy in fulfilling residue chemistry data requirements.

CONCLUSIONS/RECOMMENDATIONS

- 1) The qualitative nature of the residue in plants is sufficiently delineated considering the potential metabolites of metaldehyde and their toxicities. The metaldehyde strawberry study shows that the parent or its primary degradates translocate from soil into plant tissues and therefore represents a food use. Radioactivity from soil-applied [^{14}C]metaldehyde accumulated in strawberry fruit and leaves to maximum levels of 0.015 and 0.018 ppm on day 56 of the 98-day study. Radioactivity was also detected in the fruit (0.003 ppm) and leaves (0.006 ppm) of control plants located in the proximity of the treated soil, but planted in separate containers. The registrant contends that the radioactivity in treated and untreated plants resulted from incorporation of [^{14}C]CO₂ generated by soil microbial degradation. The HED Metabolism Committee has concluded that, due to the nature of metaldehyde, there is no need for additional plant or animal metabolism studies.
- 2) The HED Metabolism Committee has also determined that, due to its toxicity, metaldehyde should be regulated via tolerances in terms of metaldehyde per se. Attached please find the documents relating to the HED Metabolism Committee decision.

Based on the conclusions discussed above, Residue Chemistry Guideline requirement 171-4 (a) (Nature of the Residue In Plants) is fulfilled. Requirements 171-4 (b) (Nature of the Residue in Animals), 171-4 (d) (Residue Analytical Methods- Animals) and 171-4 (j) (Meat/Milk/ Poultry/ Eggs) are waived. The remaining data requirements include 171-4 (c) (Residue Analytical- Plants) and 171-4 (k) (Crop Field Trials). Guideline 171-4 (i) (Processed Food/Feed) will be reserved until such time as the results of the crop field trials are submitted and reviewed. With respect to the analytical method, residue data should be obtained utilizing a procedure which will distinguish metaldehyde from acetaldehyde, i.e. it.

should be able to detect metaldehyde in the presence of acetaldehyde. This method should be adequately validated by an independent laboratory and must undergo a successful Agency method trial in order that it can serve as an enforcement procedure. For additional requirements regarding analytical methods, see the metaldehyde Residue Chemistry chapter dated 10/7/88. Crop field trials should be carried out on representative crops in each crop grouping and certain miscellaneous commodities. Again, for further details please see the Residue Chemistry chapter cited above.

DETAILED CONSIDERATIONS

Lonza, Inc. (1991; MRID 42092701) submitted data from a soil application study of [^{14}C]metaldehyde on strawberries. A simulation of the 4% RTU formulation was prepared by mixing [^{14}C]metaldehyde (radiochemical purity 99.95%, specific radioactivity 4.2 mCi/mmol) with the viscous liquid formulation matrix (minus the active ingredient). The test substance was applied on sandy soil in a planter box containing 12 strawberry plants. Dime-sized spots of the formulation were placed 1 ft apart, 9 inches from the foliage line at a rate equivalent to 1.28 lb ai/A (1x the maximum rate for this 4% RTU formulation on numerous food sites). Plexiglass sheets, 12 feet high, were positioned upright at the foliage lines and at the edges of the planter box to prevent splashing of the liquid formulation onto the plants during application and watering. Pots of control plants were placed beside the test planter box. To maximize the potential for translocation, the entire planter box was watered, including the area of application, instead of directing the water to the base of the plants as would be done in commercial practice. The plants were treated with a miticide and Osmocite R 15-15-15 to avoid bacterial and fungal diseases. To test the volatility of the active ingredient, 16 dime-sized spots of formulation were each placed on soil in a plastic weighing boat and one sample was analyzed at each of the plant sample collection intervals.

Fruit and leaves were collected at 1, 7, and 14 days after treatment and thereafter at 2-week intervals up to 98 days (some labels specify a 6-day PHI for vegetables and strawberries and 30 days for cereal grains; one label states a 14-day PHI for citrus). At the end of the study, a 18-inch soil core from each treatment spot was collected and the formulation spot, or top layer of soil if the spot was not identifiable, was collected. Successful collection of the remaining ^{14}C -activity was determined by lack of response from a Geiger counter. The remaining soil was then subsampled at 0-6, 6-12, and 12-18 inch depths. The formulation spot and other soil samples were pulverized with liquid nitrogen, combusted, and radioassayed by liquid scintillation spectrometry (LSS).

Fruit and leaf samples were rinsed in 40 mL of water, then homogenized with water. An aliquot of each homogenate was combusted and rinsates and combusted samples were radioassayed by LSS. The detection limit of the radioassay was 0.001 ppm.

Total Radioactive Residues (TRR) in Strawberry Tissues

Radioactivity in the rinsates, representing surface residues, were reported as dpm/mL and were reported for controls and treated samples from each collection interval. Values reported were 0-5 dpm/mL for control fruit and leaves and 0-4 dpm/mL for treated samples.

The radioactivity detected in fruit and leaf homogenates at each collection interval are reported in Table 1. Low levels of ^{14}C -activity accumulated in treated fruit and leaves over time, first becoming detectable at 14 days and reaching >0.01 ppm levels at 42 days in leaves and 56 days in fruit. Very low levels of radioactivity were detected in control samples after 14 days in leaves and 56 days in fruit. No additional analyses were conducted to characterize radioactive residues.

The registrant contended that the radioactivity in both treated and control plants was due to the incorporation of $[^{14}\text{C}]\text{CO}_2$ from soil microbial breakdown into natural products. To support this claim, the registrant noted that radioactivity in the control samples could result only from incorporation of volatile radioactivity because the control plants were outside the treated planter box but near the treated soil. The higher levels of radioactivity in the treated plants were explained by their closer proximity to the treated soil spots. To further support the theory of $[^{14}\text{C}]\text{CO}_2$ incorporation, the registrant included the results of the soil analyses from this study and also data from environmental fate degradation studies.

Table 1. ¹⁴C-Residues in plants at various time intervals.

Day	Untreated		Treated	
	Fruit	Leaves	Fruit	Leaves
	-----Residues (ppm)-----			
1	<0.001	<0.001	<0.001	0.001
7	<0.001	<0.001	<0.001	0.002
14	<0.001	0.001	0.001	0.003
28	<0.001	0.001	0.004	0.004
42	<0.001	0.002	0.008	0.012
56	0.003	0.005	0.015	0.018
70	0.001	0.002	0.009	0.013
84	0.001	0.002	0.001	0.017
98	0.001	0.006	0.006	0.017

Degradation and Movement of Radioactive Residues in Soil and Air

The results of the soil volatility analyses are summarized in Table 2. The recovery of the radioactivity initially applied to soil in weighing boats decreased to about half the initial level after 70 days. Recovery of applied radioactivity from the planter box formulation spots at the termination of the experiment (98 days), however, were higher, 61.2-93%, with an average of 75.1%. The registrant did not explain these higher recoveries. The use of fungicide on the test plants could have retarded microbial degradation in the planter box, whereas no mention was made of applying fungicide to the soil in the weighing boats.

Table 2. Recovery of radioactivity from the soil volatility study at various time intervals.

Time interval (day)	Average % dose recovered
0	98.2
1	77.0
7	82.9
14	84.0
28	75.7
42	53.0
56	58.5
70	47.3

Data from an environmental fate soil degradation study were included in the submission and pertinent data are presented in Table 3. The time intervals in Table 3 were selected from the year-long study as representative of the few specified PHIs for metaldehyde and the interval covered by the current strawberry study. The total radioactivity remaining in soil at 89 days was 72.6%, a value consistent with the average 75% remaining after 98 days in the strawberry study. After 89 days, total volatiles accounted for only 23.4% of the applied radioactivity, most of which (18.6%) was in the first potassium hydroxide (CO₂) trap. Based on radioactivity in the ethylene glycol trap, the data indicate that at 30 days or less after soil application of metaldehyde, 2.5% of the applied chemical could consist of the parent or primary degradates. In the current study, at the 98-day interval these residues accumulated to about 5%.

The strawberry metabolism study is sufficient to determine that metaldehyde or its primary degradates translocate from registered soil application into plant tissues. The study demonstrates that the use of metaldehyde on crops is a food use.

Table 3. Distribution of ¹⁴C-residues of metaldehyde during the aerobic soil metabolism study.

Study day	7	14	30	89
	-----Percent of Dose-----			
Total ¹⁴ C-accountability	102.4	98.7	95.8	96.0
<u>Accumulative volatiles*</u>				
Et	0.7	1.2	2.5	4.8
K ₁	2.4	3.9	7.5	18.6
K ₂	0.0	0.0	0.0	0.0
Total	3.1	5.1	10.0	23.4
Non-extractable residues	4.1	5.4	8.1	8.1
Extractable residues	95.2	88.2	77.7	64.5

*Et = ethylene glycol trapping solution; K₁ = first KOH trapping solution; K₂ = second KOH trapping solution.

References

Citations for the MRID documents referenced in this review are presented below. Submissions reviewed in this document are indicated by shaded type.

- 42092701 Selim, S. (1991) Evaluation of the Potential for Metaldehyde or its Degradates to Translocate into Strawberry Plants Following Ground Application of a Liquid Metaldehyde Formulation: Lab Project Number: P01991. Unpublished study prepared by Biological Test Center. 116 p.

Agency Memoranda

CB No. 6322
Subject: Lonza Inc. Response to the Metaldehyde Reregistration Standard: Plant Metabolism Study Protocol.
To: R. Engler
From: R.B. Perfetti
Dated: 4/18/90
MRID(s): none.

CB No. none
Subject: 84-WI-02. Section 18 emergency exemption for the use of metaldehyde on ginseng.
To: D.R. Stubbs
From: S. Malak
Dated: 4/06/84
MRID(s): none

Metalddehyde (CASE 576)
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 9/11/92¹
REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH
CODEX²

Guideline Number and Topic ³	Phase V data requirements satisfied?	MRID(s) ⁴
171-3 Directions for use	N	
171-4(a) Plant Metabolism	N/A ⁵	42092701
171-4(b) Animal Metabolism	N/A	
171-4(c) Residue Analytical Methods - Plants	N	
171-4(d) Residue Analytical Methods - Animals	N/A	
171-4(e) Storage Stability	N	
171-4(k) Crop Field Trials		
171-4(k) Root and Tuber Vegetables Group	N	
171-4(k) Leaves of Root and Tuber Vegetables	N	
171-4(k) Bulb Vegetables Group	N	
171-4(k) Leafy Vegetables (except Brassica)	N	
171-4(k) Brassica Leafy Vegetables Group	N	
171-4(k) Legume Vegetables (succulent/dried)	N	
171-4(k) Foliage of Legume Vegetables	N	
171-4(k) Fruiting Vegetables Group	N	
171-4(k) Cucurbit Vegetables Group	N	
171-4(k) Citrus Fruits Group [see 171-4(l)]	N	
171-4(k) Pome Fruits Group	N	
171-4(k) Stone Fruits Group	N	
171-4(k) Small Fruits and Berries Group	N	
171-4(k) Tree Nuts Group	N	
171-4(k) Cereal Grains Group	N	
171-4(k) Forage, Fodder, and Straw of Cereal Grains	N	
171-4(k) Grass Forage, Fodder, and Hay Group	N	
171-4(k) Non-grass Animal Feeds	N	
171-4(k) Herbs and Spices Group [see 171-4(l)]	N	
171-4(k) Miscellaneous Commodities		
Asparagus	N	
Avocados	N	
Bananas	N	
Artichokes (globe)	N	
Mint [see 171-4(l)]	N	
Okra	N	
Tobacco	N	
171-4(l) Processed Food/Feed		

Metalddehyde (CASE 576)
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 9/11/92¹
REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH
CODEX²

Guideline Number and Topic ³	Phase V data requirements satisfied?	MRID(s) ⁴
171-3 Directions for use	N	
171-4(a) Plant Metabolism	N/A ⁵	42092701
171-4(b) Animal Metabolism	N/A	
171-4(c) Residue Analytical Methods - Plants	N	
171-4(d) Residue Analytical Methods - Animals	N/A	
171-4(e) Storage Stability	N	
171-4(k) Crop Field Trials		
171-4(k) Root and Tuber Vegetables Group	N	
171-4(k) Leaves of Root and Tuber Vegetables	N	
171-4(k) Bulb Vegetables Group	N	
171-4(k) Leafy Vegetables (except Brassica)	N	
171-4(k) Brassica Leafy Vegetables Group	N	
171-4(k) Legume Vegetables (succulent/dried)	N	
171-4(k) Foliage of Legume Vegetables	N	
171-4(k) Fruiting Vegetables Group	N	
171-4(k) Cucurbit Vegetables Group	N	
171-4(k) Citrus Fruits Group [see 171-4(l)]	N	
171-4(k) Pome Fruits Group	N	
171-4(k) Stone Fruits Group	N	
171-4(k) Small Fruits and Berries Group	N	
171-4(k) Tree Nuts Group	N	
171-4(k) Cereal Grains Group	N	
171-4(k) Forage, Fodder, and Straw of Cereal Grains	N	
171-4(k) Grass Forage, Fodder, and Hay Group	N	
171-4(k) Non-grass Animal Feeds	N	
171-4(k) Herbs and Spices Group [see 171-4(l)]	N	
171-4(k) Miscellaneous Commodities		
Asparagus	N	
Avocados	N	
Bananas	N	
Artichokes (globe)	N	
Mint [see 171-4(l)]	N	
Okra	N	
Tobacco	N	
171-4(l) Processed Food/Feed		

Metaldehyde (CASE 576)
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 9/11/92¹
REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH
CODEX²

Guideline Number and Topic ³	Phase V data requirements satisfied?	MRID(s) ⁴
Alfalfa	R ⁵	
Apples	R	
Beans (succulent/dried)	R	
Citrus	R	
Corn, Field	R	
Corn, Fresh	R	
Grapes	R	
Mint	R	
Oats	R	
Plums	R	
Potato	R	
Rice	R	
Sorghum, grain	R	
Sorghum, sweet	R	
Soybeans	R	
Spices	R	
Sugar beets	R	
Tomato	R	
Wheat	R	
171-4(j) Meat/Milk/Poultry/Eggs	N/A	
171-4(f) Potable Water	N/A	
171-4(g) Fish	N/A	
171-4(h) Irrigated Crops	N/A	
171-4(l) Food Handling Establishments	N/A	
171-5 Reduction of Residues	N/A	

¹ Reregistration Standard Chapter issued 10/7/88. No Reregistration Standard Update issued {date}.

² There are no Codex MRL's established for metaldehyde, therefore no harmonization questions exist for this chemical.

³ N/A = Guideline requirement not applicable.

⁴ MRIDs that were reviewed in the current submission are designated in shaded type.

⁵ RBP, CBRS# 9200, 9/11/92. The qualitative nature of the residue in plants is sufficiently delineated considering the potential metabolites of metaldehyde and their toxicities. metaldehyde strawberry study shows that metaldehyde or its primary degradates translocate from soil into plant tissues and therefore represents a food use. The HED Metabolism Committee has concluded that due to the nature of metaldehyde, there is no need for additional plant or animal metabolism studies. The HED Metabolism Committee has also determined that, due to its toxicity, metaldehyde should be regulated via tolerances in terms of metaldehyde per se.

Residue Chemistry Guideline requirement 171-4 (a) (Nature of the Residue in Plants) is fulfilled. Requirements 171-4 (b) (Nature of the Residue in Plants) , 171-4 (d) (Residue Analytical Methods- Animals) and 171-4 (j) (Meat/Milk/ Poultry/ Eggs) are waived. The remaining data requirements include 171-4 (c) (Residue Analytical- Plants) and 171-4 (k) (Crop Field Trials). Guideline 171-4 (l) (Processed Food/Feed) will be reserved until such time as the results of the crop field trials are submitted and reviewed. With respect to the analytical method, residue data should be obtained utilizing a procedure which will distinguish metaldehyde from acetaldehyde, i.e. it should be able to detect metaldehyde in the presence of acetaldehyde. This method should be adequately validated by an independent laboratory and must undergo a successful Agency method trial in order that it can serve as an enforcement procedure. For additional requirements regarding analytical methods, see the metaldehyde Residue Chemistry chapter dated 10/7/88. Crop field trials should be carried out on representative crops in each crop grouping and certain miscellaneous commodities. Again, for further details please see the Residue Chemistry chapter cited above.

* R = Reserved.

cc: RBP; Reregistration Standard File for Metaldehyde; Lois Rossi, SRRD

MAY 4 1993

Mr. Joseph R. Robinson
Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Dear Mr. Robinson:

Subject: Metaldehyde Reregistration
Strawberry Translocation Study and Status of Residue
Chemistry Data Requirements and Time Extensions
for Soil Volatility and Avian Reproduction Studies
Your Letters Dated November 7, 1991, and June 24,
and December 4, 1992

The qualitative nature of the residue in plants is sufficiently defined considering the potential metabolites of metaldehyde and their toxicities. The metaldehyde strawberry study (MRID# 42092701) shows that the parent or its primary degradates translocate from soil into plant tissues and therefore represents a food use. The Agency has concluded that, due to the nature of metaldehyde, there is no need for additional plant or animal metabolism studies. However, the Agency has also determined that, due to its toxicity, metaldehyde should be regulated via tolerances in terms of metaldehyde per se.

Based on this information, the EPA Residue Chemistry Guideline Requirements are as follows:

171-4(a)	Nature of Residue-Plants	Satisfied
171-4(b)	Nature of Residue-Animals	Waived
171-4(c)	Residue Analytical Methods-Plants	Need Data
171-4(d)	Residue Analytical Methods-Animal	Waived
171-4(j)	Meat/Milk/Poultry/Eggs	Waived
171-4(k)	Crop Field Trials	Need Data
171-4(l)	Processed Food/Feed	Reserved

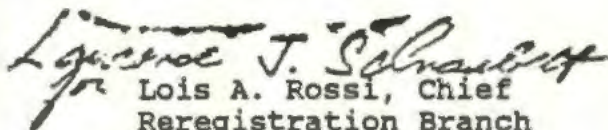
With respect to the analytical method, residue data should be obtained utilizing a procedure which will detect metaldehyde in the presence of acetaldehyde. Crop field trials should be carried out on representative crops in each crop grouping and certain miscellaneous commodities. For further details refer to the attached Residue Chemistry chapter dated 10/7/88 and the Data Evaluation Record Dated September 14, 1992.

-2-

The requests for time extensions for the Soil Volatility (EPA Guideline 163-2) to 3/30/93 and the avian reproduction studies (EPA Guidelines 71-4 (a) & (b)) to 5/30/93 are acceptable.

Attached is a copy of the Data Evaluation Record for your records. Within 30 days of receipt of this letter, please provide the Agency with a schedule for submission of these data. Questions concerning this letter should be addressed to Mr. Robert Richards in the Office of Pesticide Programs, Reregistration Branch at (703) 308-8057.

Sincerely,


Lois A. Rossi, Chief
Reregistration Branch
Special Review and
Reregistration Division

Enclosures

cc: Dennis Edwards/RD

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 5 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Metaldehyde. Conclusions of Meeting Between OPP
and Lonza Inc.
No MRID No CB Number No DP Barcode

From: Michael S. Metzger, Branch Senior Scientist
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

Thru: Edward Zager, Chief
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

To: Esther Saito, Ph.D., Chief
Reregistration Branch
Special Review and Reregistration Division (7508W)

Representatives of OPP (E. Saito, R. Richards, R. Perfetti, M. Metzger) met with representatives of Lonza, Inc. (Burton Eisenberg, Joseph Robinson) and consultants to Lonza (Gerald Schoenig, Toxicology/Regulatory Services, S. Schatzow) to discuss residue chemistry data requirements for Metaldehyde.

The registrant and their consultants presented the same information presented at an earlier meeting (7/19/93). In summary, the only residue chemistry data available for metaldehyde is a single strawberry metabolism study in which only the TRR was determined, i.e., residues were not further characterized or identified. The registrant states that the radioactivity found in treated strawberries is due to uptake of radioactive ¹⁴C from soil-metabolized metaldehyde. Information to support this conclusion included radioactivity found in control plants grown near the treated plants, and low measured vaporization of metaldehyde. The registrant indicated that use of metaldehyde should be considered a non-food use. The registrant states that the strawberry metabolism study is a worst case in terms of potential residues in plants. Refer to the CBRS memorandum of 7/28/93 for additional details (M. Metzger).

CBRS concluded the following:



cc: Metaldehyde SF, Reg Std File, RF, Circu
RDI:EZ:12/13/94
7509C:M.Metzger:MM:CBRS:Rm816G:CM#2:(703)305-5883:12/13/94

13/94

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 3 1995

CERTIFIED MAIL

Joseph R. Robinson
Lonza, Inc.
Corporate Headquarters
17-17 Route 208
Fair Lawn, NJ 07410

Dear Mr. Robinson:

Subject: Metaldehyde Registration Standard
Plant Metabolism and Residue Field Trial Data
Requirements (EPA Guidelines 171-4A&K)

The Agency has reconsidered its position regarding metabolism and residue data requirements for metaldehyde and therefore is requiring the following:

- 1) Two additional plant metabolism studies should be done, preferably exaggerated rate studies, in which residues of parent metaldehyde are determined. The Agency recommends that leaf lettuce and sugar beets (roots and tops) be used in these studies.
- 2) If no detectable residues of metaldehyde are found, an enforcement analytical method must be developed and LOQ tolerances will be established. Field trial data and processing data will not be required.
- 3) If detectable residues of metaldehyde are found, field trial and processing data, and possibly other residue chemistry data, will be required.

Because of the way metaldehyde is used, the Agency believes there is a reasonable possibility the pesticide will come into contact with the plant and residues in foods could result. Therefore, these uses cannot be considered non-food uses. In addition, the Metabolism Committee previously concluded that due to metaldehyde's toxicity, exemptions from the requirements of a tolerance are not appropriate and tolerances are required.

CONCURRENCES

SYMBOL	7508W	7508W					
SURNAME	<i>Richard</i>	<i>Schroeder</i>					
DATE	<i>2/2/95</i>	<i>2/2/95</i>					

-2-

Within 30 days of receipt of this letter, inform the Agency of your intentions to complete the data required above and provide a schedule for completion of this data. Refer to the attached review dated January 5, 1995 for further information. Questions regarding this letter should be addressed to Robert Richards, Office of Pesticide Programs, Reregistration Branch at (703) 308-8057.

Sincerely,

Esther C. Saito, Acting Chief
Reregistration Branch
Special Review and
Reregistration Division

Enclosure

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 18 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Metaldehyde: Plant Metabolism Protocol (No MRID #,
CBRS No. 15809, Barcode No.: D217056)

FROM: R. B. Perfetti, Ph.D., Chemist
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

THRU: E. Zager, Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

TO: W. Waldrop
Reregistration Branch
Special Review & Reregistration Division (7508W)

Lonza Inc. has submitted a protocol describing a plant metabolism study on leaf lettuce. The protocol is acceptable with the following comments:

- 1) The 10X application rate is acceptable, however the Registrant should reaffirm that the proposed treatment rate is in fact 10 times the maximum label rate.
- 2) If more than one application of metaldehyde is made to crops the study should reflect this. That is, the metabolism study application should reflect the normal worst case agricultural practice for the use of metaldehyde.
- 3) The samples should not be rinsed prior to determination of the TRR.
- 4) The Registrant is also referred to the document entitled "Additional Guidance For Conducting Plant and Livestock Metabolism Studies" (7/92).

If you need additional input please advise.

cc: RBP, Metaldehyde Reregistration Standard File, RF and Metaldehyde Subject File.



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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 24 1996

W. Neudorff GMBH KG
c/o Walter G. Talarek
1008 Riva Ridge Drive
Great Falls, VA 22066

Dear Mr. Talarek:

Subject: NEU 1165M
EPA File Symbol 67702-G
Application for Registration dated 6/10/96

In your application for registration of NEU 1165M (EPA File Symbol 67702-G), presently under review by the Biopesticides and Pollution Prevention Division (BPPD), you have maintained that the use pattern for your product and the nature of the active ingredient are such that the product should not be considered to fall within the terrestrial food-crop general-use pattern. You, therefore, did not submit a petition for exemption from the requirement of a tolerance in conjunction with your application.

The Health Effects Division (HED) is tasked with determining whether use patterns are considered food-use or non-food use for the purposes of FFDCA and FIFRA, as amended. HED has determined that the use pattern as described on the label submitted with your application for registration of NEU 1165M is considered to be food-use. A copy of the memorandum discussing this decision "EPA Reg. No. 67702-G. Determination of Food Use for Iron Phosphate used as a Slug and Snail Bait" dated Oct. 4, 1996, is included with this letter.

As discussed in the HED memorandum, registration of NEU 1165M with the uses described on the proposed label, will require a tolerance or exemption from requirement of a tolerance. At this point in time, EPA is requesting that registrants refrain from submitting tolerance requests, as the procedures for processing these applications in compliance with the new Food Quality Protection Act (FQPA) have not been finalized. The text of Dr. Lynn Goldman's letter of Sept. 6, 1996, discussing this issue is included. It is expected that the new requirements for FQPA-compliant tolerance petitions will be determined very soon. A notice detailing these requirements will be sent to all registrants. All petitions which have already been submitted to EPA will be returned to the submitters, who will be required to

CONCURRENCES						
SYMBOL	7501W	7501W				
SURNAME	Kami	Tolarek				
DATE	10/22/96	10-23-96				

After the FQPA issues are resolved, you must submit a petition for a tolerance or exemption from the requirement of a tolerance. The consideration of your application for registration of NEU 1165M will not proceed until the tolerance/exemption has been granted.

As an alternative to requesting a tolerance decision before registering NEU 1165M, you may wish to consider proceeding with the application by revising your label to restrict application of NEU 1165M to ornamental plants &/or home gardens. These uses are not considered food-use and do not require a tolerance decision. After the FQPA issues have been resolved, you could apply for an exemption from tolerance and, if granted, apply for an amendment to reinstate the food uses on the label.

Please note that the product chemistry studies submitted by Madison Chemicals, Inc. in support of the NEU 1165M application have been found to be in full compliance with the standards for submission of data contained in PR Notice 86-5 by the Document Processing Desk. The Master Record Identification (MRID) numbers assigned to the studies are as follows:

Analysis and Certification of Product Ingredients: MRID 441319-01

Product Identity and Composition: MRID number 440734-01.

Any questions may be directed to Joan Karrie, Regulatory Action Leader for this action, at (703) 308-8699, fax (703) 308-7026.

Sincerely,

Janet L. Andersen, Ph.D.
Acting Director
Biopesticides and Pollution
Prevention Division (7501W)

enclosures

JKarrie/CS1/308-8699/10-23-96/

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

OCT 10 1996

MADISON CHEMICALS, INC.
P.O. BOX 194
OLD BRIDGE, NJ 08857

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/08/96. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



441319-00

MADISON CHEMICALS, INC.

OLD WATERWORKS ROAD, MADISON TOWNSHIP, N.J.

MAILING ADDRESS: P.O. BOX 194, OLD BRIDGE, N.J. 08857 • TELEPHONE: (908) 727-2232

FAX: (908) 727-2653

August 16, 1996

Dr. Janet Anderson
Product Manager, Team 90
Office of Pesticide Programs (APPL)
Document Processing Desk (H7504C)
Environmental Protection Agency
401 M Street, S. W.
Washington, D.C. 20460

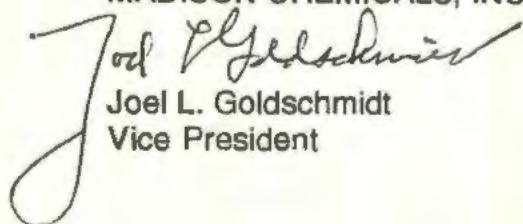
Reference: Application for Registration of NEU 1165M
EPA File Symbol 67702-G

Dear Dr. Anderson

Madison Chemicals, Incorporated ("Madison") is hereby re-submitting Volume 3; 44131901
Product Chemistry, Analysis and Certification of Product Ingredients. We received a
telephone call from Joan Karri indicating that we had not signed the origian
submission. Enclosed you will find three signed copies.

Feel free to call me should you have any questions.

Yours truly,
MADISON CHEMICALS, INC.


Joel L. Goldschmidt
Vice President



MADISON CHEMICALS, INC.

OLD WATERWORKS ROAD, MADISON TOWNSHIP, N.J.

MAILING ADDRESS: P.O. BOX 194, OLD BRIDGE, N.J. 08857 • TELEPHONE: (908) 727-2232

FAX: (908) 727-2653

October 1, 1996

Dr. Janet Anderson
Product Manager , Team 90
Office of Pesticide Programs (APPL)
Document Processing Desk (H7504C)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C.20460

Subject:: Application for Registration of NEU 1165m
EPA File Symbol 67702-G

Dear Dr. Anderson:

In response to your letter of September 18, 1996, a copy of which is enclosed, we are enclosing three copies of the rejected study (03).

We hope and trust that this fills the requirements of the EPA.

Yours truly,
MADISON CHEMICALS, INC.


Joel L. Goldschmidt
Vice President

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 18 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Madison Chemicals, Inc.
C/O Joel L. Goldschmidt
P.O. Box 194
Old Bridge, N.J. 08857

Subject: Rejection of Application for Registration of NEU 1165m
EPA File Symbol 67702-G

Dear Mr. Goldschmidt:

As you may already know, all data submitted to the Agency to support registration actions must conform to a standard format, organization, and other requirements described in Pesticide Registration Notice (PRN) 86-5 dated July 29, 1986. This notice was mailed to all registrants on record with the Agency at that time.

All incoming data are screened for compliance with the PR Notice. Data that are in compliance are assigned master Record Identification Numbers (MRIDs) microfilmed, and forwarded for appropriate action. Data that do not comply with the requirements of the Notice are not admitted into the system. Such data must be brought into compliance with the PR Notice before the data can be given further consideration in support of the regulatory action for which the data were submitted.

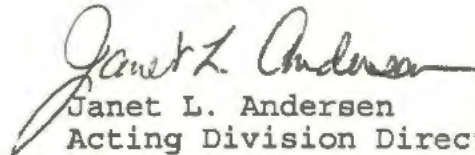
The data submitted in connection with the proposed action listed above have been found deficient with respect to the requirements of PRN 86-5. The deficiencies are identified in the enclosed comments from the Information Services Branch of the Program Management and Support Division.

Biopesticides and Pollution Prevention Division will hold associated documents for 75 days to give opportunity to resubmit the supporting data in acceptable form. If you have not done so by that time, the application and other associated documents may be administratively withdrawn from further consideration without notice to you, in accordance with policies established by PR Notice 75-4 dated August 27, 1975.

Should you wish to pursue the registration of your product after the application has been withdrawn you will have to submit a complete new application.

If you choose to resubmit your data you should enclose a copy of the letter and the enclosure to identify the data as a corrected resubmission of data previously found deficient with respect to PRN 86-5. Only resubmit those items of data for which no MRID numbers were assigned. If any of your previous items was assigned an MRID number, do not resubmit that particular item of data, but simply refer to it by title and by the assigned MRID number.

Sincerely,



Janet L. Andersen
Acting Division Director
Biopesticides and Pollution
Prevention Division 7501W

Enclosure(s)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 4 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 67702-G. Determination of Food Use for Iron Phosphate used as a Slug and Snail Bait.

DPCode: D228227
Chem: 034903
CAS: 10045-86-0
CBTS: 17405
MRID: None.

FROM: R. W. Cook, Chemist *RW Cook*
Chemistry Branch 1 - Tolerance Support
Health Effects Division (7509C)

THRU: Elizabeth T. Haeberer, Acting Branch Chief *Elizabeth T. Haeberer*
Chemistry Branch 1 - Tolerance Support
Health Effects Division (7509C)

TO: Janet Anderson/Joan Karrie, PM 90
BPPD (7507C)

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY CONCLUSIONS

- The use pattern, as described by the applicant's letter of 6/10/96 is considered to be a 'food use', when used on food crops. This use requires either a tolerance for residues or exemption from the requirements of a tolerance. We expect, TOX considerations permitting, that exemption from the requirements of tolerance is appropriate.

BACKGROUND

We have been asked by BPPD to determine whether the proposed use pattern is a non-food use.

The applicant has argued in their letter (6/10/96, Walter G. Talarek, Esq. to Janet Anderson, BPPD) that another pesticide chemical used as a slug and snail molluscicide, metaldehyde, does not have a tolerance or exemption from tolerance. We note that this statement is incorrect; a food additive tolerance has been established for residues of metaldehyde per se in strawberries under 40 CFR 185.4025. The established tolerance is 'zero' ppm. The Metaldehyde Registration Standard Residue Chemistry Chapter (10/88) indicates that uses of a pesticide to kill slugs and snails on food crops are, in fact, 'food uses' requiring either tolerance or exemption from the requirement of tolerance.



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CONCLUSIONS

Based upon proposed uses, the use of iron phosphate is a "food use" and therefore subject to regulation under FFDCA and FIFRA, as amended. In conjunction with the later, HED notes that the Food Quality Protection Act of 1996 has amended and strengthened the standard for establishing tolerances under the FFDCA. OPP is still assessing the full impact of this change in the law on the tolerance-setting process and plans to issue guidelines concerning the establishment of tolerances under the amended statute. All tolerance petitions have to meet the requirements of the FFDCA as amended by the FQPA and OPP may require additional data to determine if the terms of the amended statute are met.

If the use of the bait were clearly limited to home gardens (i.e., crops which would not move in commerce), a tolerance or exemption from tolerance under FFDCA may not be required. However, potential dietary exposure to homeowners would still be assessed under FIFRA.

RECOMMENDATIONS

The applicant should be informed that the proposed use is a food use and is subject to the tolerance or exemption from tolerance requirements of FFDCA and FIFRA, as amended. We expect, TOX considerations permitting, that exemption from the requirements of tolerance is appropriate.

DETAILED CONSIDERATIONS

Directions For Use:

The pertinent detailed use directions are included below:

NEU 1165M Slug and Snail Bait:

HOW TO APPLY: The slug bait granules should be scattered on the soil around or near the plants to be protected. Apply baits evenly at approximately 1 lb. per 1000 square feet (0.15 oz. or about 1 level tablespoon, per square yard) and reapply as the bait is consumed or at least every two weeks. Do not place in piles. If the ground is dry, wet it before applying bait. The soil should be moist but with little or no standing water.

Reapply as the bait is consumed or at least every two weeks. Apply more heavily if the infestation is severe, if the area is heavily watered or after long periods of heavy rain. Apply only to the soil surface around plants, do not apply to foliage or other plant parts. See specific directions for different plant types and for inside green houses.

WHEN TO APPLY: Evening is the best time to apply the bait, as slugs and snails travel and feed mostly by night or early morning.

WHERE TO APPLY: All likely areas of infestation should be treated, especially around the perimeter of garden plots because these pests travel into plant area from daytime refuges. They favor damp places around vegetable plants such as beans, tomatoes, lettuce, cabbage, celery and squash. Other favorite areas are flower gardens, rockeries, hedges, dichondra lawns, citrus groves, ivy patches, and other ground cover where they obtain shelter by day.

OUTDOOR ORNAMENTALS

Scatter bait in a 6 inch circular band around the base of the plants to be protected at 0.15 oz, or 1 level tablespoon, per square yard. If plants are next to a grassy area, spread the bait between the ornamental and the grass. Slugs traveling to the plants will encounter the bait before reaching the plant. Scatter the bait around the perimeter of the plot at approximately 1 lb. per 1000 square feet to intercept snails and slugs travelling to the plot.

Vegetables

The bait can be used to protect any vegetables from slug and snail damage, including (but not limited to): artichokes, asparagus, beans, beets, blackeyed peas, broccoli, brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, corn, cucumbers, eggplants, garlic, lettuce, onions, peas, peppers, potatoes, radishes, spinach, squash, Swiss chard, tomatoes, and turnips. Do not put the bait on the plant. Scatter the bait around the perimeter of the vegetable plot at approximately 1 lb. per 1000 square feet to provide a protective barrier for slugs entering the garden plot. If slugs are inside the rows, then scatter the bait on the soil around the base of the plants and between the rows.

Fruits Including Citrus.

The bait can be used to protect fruits from slugs and snails, including (but not limited to): apples, avocados, apricots, cherries, grapes, melons, peaches, plums, citrus, pears. For seedling spread the bait around the base of the stem, without touching the plant. Apply at 0.15 oz. or 1 level tablespoon, per square yard, in a 6 inch circular band around the base of the plants to be protected. For older trees, spread the bait around the base of the tree to intercept slugs and snails traveling to the trunk. Apply the bait at approximately 1 lb. per 1000 square feet for orchards using standard fertilizer granular spreaders.

Berries

The bait can be used to protect berries from slugs and snails including (but not limited to): strawberries, blackberries, blueberries, boysenberries, loganberries, raspberries. Do not apply the baits on the plants. Spread the bait around the perimeter of the plot to intercept slugs and snails migrating toward the berries. Use a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders. If slugs and snails are already in the plots, then carefully spread bait between the furrows near the base of the plants. For small plots, treat around the base of the plants to be protected. Do not spread over the entire area but apply selectively.

Field crops

The bait can be used to protect field crops from slugs and snails, including: artichokes, beans, field corn, sweet corn, potatoes, soybeans, sugarbeets, sugar cane, wheat, asparagus, beets, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, cucumbers, lettuce, onions, peas, peppers, potatoes, radishes, strawberries, tomatoes, turnips and wheat. Do not apply the bait on the plants. At the seedling stage, apply the bait between the rows and around the perimeter of the field. Scatter pellets at a rate of 44 lbs. per acre.

Greenhouses

Where snails are a problem in the greenhouse, scatter the bait in the plant pots of plants being damaged or around pots on greenhouse benches. Apply about 1/2 teaspoon per 9 inch pot. Do not put the bait on the plant.

Comments on Directions for Use/Labeling

Generally speaking, use of pesticides on domestic areas such as home gardens and lawns do not require establishment of tolerances. These food crops are grown for personal or family consumption and are unlikely to enter commerce. Uses in green houses also do not require tolerances, unless the use directions clearly indicate that a food crop grown for commercial production, i. e. greenhouse tomatoes, hydroponic cucumbers, etc., is to be treated.

The proposed use on fruits including citrus appears to be more commercial, since the use directions suggest using "... for orchards using standard fertilizer granular spreaders." The terms "orchards" and "standard fertilizer spreader" suggest larger scale commercial production. The directions for use could possibly be modified to clearly limit use to non-commercial fruits such that a tolerance or exemption would not be needed.

The proposed use on "field crops" is a food use requiring a tolerance or exemption from tolerance. The application rate is given in standard agricultural terms of 'pounds per acre'. Certain of the crops suggested under "Field Crops" are unlikely to be grown for personal use, including field corn, soybeans, sugarbeets, and wheat.

Conclusions on Directions for Use/Labeling

The proposed use on crops determines that this use is a "food use".

Food uses of pesticide chemicals require either a tolerance for residues of the pesticide, or exemption from the requirements of tolerance. If the use of the bait were clearly limited to home gardens (i.e., crops which would not move in commerce), a tolerance or exemption from tolerance under FFDCA may not be required. However, potential dietary exposure to homeowners would still be assessed under FIFRA.

Nature of the Residue

The applicant has not submitted any information regarding possible residues of iron phosphate on crops treated as proposed. The applicant indicates that iron phosphate is commonly used as a fertilizer ingredient and as a human nutritional supplement.

cc Circ., R.F., R.W.Cook. RCAB (Debbie McCall)

7509C:Reviewer:RWCook: rwc:9/24/96

RDI:tpt1:9/26/96:RALoranger:10/2/96:E. Haeberer:10/3/96

WALTER G. TALAREK, P.C.

1008 Riva Ridge Drive
Great Falls, VA 22066
USA

Tel. No. (703) 759-4837
FAX No. (703) 759-5548

TO: Ms. Joan Karrie
Bio-Pesticides and Pollution Prevention Division (7501W)

COMPANY: Environmental Protection Agency

DATE: November 13, 1996

FAX NO.: (703) 308-7026

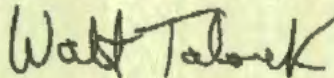
PAGES: 3

Dear Joan:

I am forwarding a recent label for Drexel Chemical Company's Slug and Snail Bait product, which has metaldehyde as the active ingredient, and which lists agricultural food crop uses for which EPA has not granted tolerances or an exemption from the requirement for a tolerance. If EPA considers the slug and snail bait use to be an agricultural food crop use, then this product, as well as other metaldehyde products with similar food crop uses, should not be registered.

Neudorff respectfully requests that EPA reconsider its position on the classification of the use pattern of its iron phosphate slug and snail bait product as an agricultural food crop use. The status of this chemical as a FDA GRAS food nutrient and supplement, status as a plant nutrient, the chemical's insolubility in water and fate in the environment, and the directions for use for Neudorff's formulated product would indicate that the agricultural food crop use classification is inappropriate for this product.

Sincerely yours,



Walter G. Talarek

Enclosure

cc: Catherine Stewart

NOV 12 '96 16:43 DREXEL CHEMICAL MEMPHIS

P.2

Drexel

Slug and Snail Bait

ACTIVE INGREDIENT:

Metaldehyde (2,3,6,8 - Tetramethyl-1,3,5,7

-Tetraoxacyclo-octane)

4.0%

INERT INGREDIENTS:

96.0%

TOTAL:

100.0%

CAUTION

It is used no extends to equets, bueque a signen pars oue a is eplique e
uted en detale. (If you do not understand this label, find someone to explain
it to you in detail.

KEEP OUT OF REACH OF CHILDREN

Read Entire Label Before Using This Product

**THIS PESTICIDE MAY BE FATAL TO DOGS OR OTHER PETS IF
EATEN. KEEP PETS OUT OF TREATED AREA.**

EPA Reg. No.: 19713-389

EPA Est. No.: 19713-GA-1

© 2000-2006

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Drink 1 to 2 glasses of water and induce vomiting by
touching back of throat with finger. Do not induce vomiting or give anything
by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water for at least 15 minutes and
get medical attention immediately.

IF ON SKIN: Wash thoroughly with soap and water.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING: Harmful if swallowed. Avoid breathing dust. May cause eye
irritation. Avoid contact with skin, eyes or clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

Coveralls

Waterproof gloves

Shoes plus socks

Follow Manufacturer's instructions for cleaning/maintaining PPE. If no
such instructions for washables, use detergent and hot water. Keep and
wash PPE separately from other laundry. When handlers use closed
systems, enclosed cabs, or aircraft in a manner that meets the
requirements listed in the Worker Protection Standard (WPS) for
agricultural pesticides (40 CFR 170.240(b)(4-6)), the handler PPE
requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using
tobacco or using the toilet. Remove clothing immediately if pesticide gets
inside. Then thoroughly wash and put on clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses, do not apply directly to water, or to areas where surface water
is present or to intertidal areas below the mean high water mark. Do not
contaminate water when disposing of equipment washwaters.

GENERAL INFORMATION

EFFECTIVE: SLUGS AND SNAIL BAIT excels at attracting and destroying slugs
and snails.

LONG LASTING: Remains effective after rain and watering. SLUG AND SNAIL
BAIT is not easily displaced by water.

NOTE: This package is filled to proper weight. Variation in product density may
result in varying full levels in the box.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its
labeling. Do not apply this product in a way that will contact workers or other
persons either directly or through drift. Only protected handlers may be in the area
during application. For any requirements specific to your state and tribe, consult
the agency responsible for pesticide regulations.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker
Protection Standard, 40 CFR Part 170. This standard contains requirements
for the protection of agricultural workers on farms, forests, nurseries, and
greenhouses, and handlers of agricultural pesticides. It contains require-
ments for training, decontamination, notification and emergency assistance.
It also contains specific instructions and exceptions pertaining to the state-
ments on this label about personal protective equipment (PPE), and re-
stricted-entry intervals. The requirements in this box only apply to uses of this
product that are covered by the Worker Protection Standard. Do not enter or
allow worker entry into treated areas during the restricted-entry interval (REI)
of 12 hours.

PPE required for entry to treated areas that is permitted under the
Worker Protection Standard and that involves contact with anything that has
been treated, such as plants, soil, or water is:

Coveralls

Waterproof gloves

Shoes plus socks

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT
within the scope of the Worker Protection Standard for agricultural
pesticides (40 CFR Part 170). The WPS applies when this product is used
to produce agricultural plants on farms, forests, nurseries, or greenhouses.
This pesticide may be fatal to dogs or other pets if eaten. Keep pets out of
treated area.

Manufactured By:
Drexel Chemical Company

P.O. BOX 13337, MEMPHIS, TN 38113-0337

EST. 1972

11/2/1996 15:01 004-556-3333

EJU NAME TECHNOLOGIES

NOV 12 '96 16:44 DREXEL CHEMICAL MEMPHIS

P.2

Apply as a soil surface treatment. May be broadcast by air or ground equipment unless specified otherwise in this label. Use a band treatment between the rows after formation of edible parts. Do not contaminate edible portions of the plant. May be applied to the following crops to protect from slugs and snails.

FIELD CROPS: Cereals/grains: corn, legumes, milo; Apply 10 to 40 lbs. per acre. **SEED CROPS:** Flaxseed, grasses, sugar beets, vegetable and legume crops grown for seed; Apply 10 to 40 lbs. per acre.

VEGETABLES: Asparagus, beans/bests, black-eye peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, celery, collards, corn, corn-peas, cucumbers, eggplants, endive, ginseng, horseradish, kale, kohlrabi, leeks, legumes, lettuce, melons, mustard greens, okra, onions, parsnips, peas, peppers, pimientos, pumpkins, radishes, rhubarb, rutabagas, salsify, shallots, spinach, squash, sweet potatoes, Swiss chard, tomatoes, turnips, watermelons; Apply 20 to 40 lbs. per acre.

Artichokes: By air or ground application before tight bud stage, apply by ground application only.

TREE CROPS: Citrus: Apply 20 to 40 lbs. per acre to give even distribution. Avocado, cherries, peaches, apricots, apples, pears; Apply 20 to 40 lbs. per acre.

SMALL FRUIT: Blackberries, blueberries, boysenberries, canberries, loganberries, raspberries, strawberries, grapes; Apply 10 to 40 lbs. per acre.

TURF AND ORNAMENTALS: Ornamental greenhouses, ornamental plantings, commercial ornamental nurseries, ground covers, turfgrass areas and grasses grown for seed, dioncortia; and around home and building foundations. Normally apply 5% to 2 lbs. per 1,000 square feet. Repeat treatment as necessary to maintain control.

For best results, apply in evening. Especially beneficial, if applied following rain or watering. Apply every 3 to 4 weeks during growing season, or as needed. **DO NOT APPLY DIRECTLY TO EDBLE PORTIONS OF THE PLANT.**

HOME AND GARDEN USE

Protects Vegetables, Flowers, and Lawns.

- Remains effective after rain and watering.

- Goes further; lasts longer.

If ground is dry, thoroughly water areas to be treated. For best results, apply in the evening. Scatter **SLUG AND SNAIL BAIT** around flowers, ornamental plants and lawn areas. Do not place **SLUG AND SNAIL BAIT** in piles. Apply one pound of **SLUG AND SNAIL BAIT** to each 1,250 square feet. Apply only to the soil surface around plants. Do not apply directly to foliage or other plant parts. See below for directions for use around fruits, berries, and vegetables.

Slugs and snails are likely to be infested at the beginning of the spring planting season before damage occurs. Treat every 3 to 4 weeks during the growing season, or as needed. During periods of high rainfall or frequent watering, it may be necessary to treat more often.

SLUG AND SNAIL BAIT is specifically formulated to attract and control snails and slugs. **SLUG AND SNAIL BAIT** is easy to use, clean to handle, and economical. One pound will bait 1,250 square feet.

The presence of snails and slugs can be detected by the shiny, mucous-like trail left by the slugs and snails. They are night feeders and prefer damp cool places in the ornamental garden, flowers, under boards or flower pots or piles of leaves, and around fences, rocks, hedges, and bushes.

FRUITS, BERRIES AND VEGETABLES: To control snails and slugs around the following fruits, berries, and vegetables, apply to the soil surface around the plants. Do not contaminate edible parts. Thoroughly wash all parts used for food before eating.

TREE FRUITS: Apples, apricots, avocado, citrus, cherries, peaches, pears.

BERRIES: Blackberries, boysenberries, canberries, loganberries, raspberries, strawberries.

VEGETABLES: Artichokes, asparagus, beans, black-eye peas, broccoli, Brussels sprouts, cabbage, cantaloupe, corn, cauliflower, celery, collards, corn-peas, cucumbers, eggplants, endive, garlic, ginseng, horseradish, kale, kohlrabi, leeks, legumes, lettuce, melons, mustard greens, okra, onions, parsnips, peas, peppers, pimientos, potatoes, pumpkins, radishes, rhubarb, rutabagas, salsify, shallots, spinach, squash, sweet potatoes, Swiss chard, tomatoes, turnips, watermelons.

FLOWERS AND ORNAMENTALS: Apply to soil surface around the following plants: Asters, begonias, carnations, chrysanthemums, daffodils, daisies, geraniums, honeysuckle, hydrangeas, ice plants, impatiens, lily, mangolds, pansies, petunias, rhododendrons, roses, snapdragons, sweet peas, tulips.

NOTE: When setting out transplants, sprinkle a small amount of **SLUG AND SNAIL BAIT** around each plant after watering. These new soil, succulent plants are very tempting to foraging snails and slugs for the first few weeks after planting.

STORAGE AND DISPOSAL

STORAGE: Do not contaminate water, food, or feed by storage or disposal. Use product only from original container and keep in locked storage area away from children and pets. Do not store near food, feed, fertilizer, or other pesticides or chemicals.

PESTICIDE DISPOSAL: Completely empty bag into application equipment. Then dispose of empty in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY - CONDITION OF SALE

OUR RECOMMENDATIONS FOR USE of this product are based upon tests believed reliable. Follow directions carefully. Timing and method of application, weather and crop conditions, mixtures with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the Seller. Buyer assumes all risks of use, storage and handling of this material not in strict accordance with directions given hereon. In no case shall Drexel or the Seller be liable for consequential, special or indirect damages resulting from the use or handling of this product when such use and/or handling is not in strict accordance with directions given hereon. This foregoing is a condition of sale by Drexel Chemical Company and is accepted as such by the Buyer.

AUG 06 1996

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

MADISON CHEMICALS, INC.
P.O. BOX 194
OLD BRIDGE, NJ 08857

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/30/96. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [03] :

- * You failed to sign the statement of data confidentiality claims included in the study.
- * You provided fewer than the required three complete copies of submitted data.

*called Madison chemicals
8/16/96* *JK*

*Sent study back
10/1/96* *JK*



MADISON CHEMICALS, INC.

OLD WATERWORKS ROAD, MADISON TOWNSHIP, N.J.

MAILING ADDRESS: P.O. BOX 194, OLD BRIDGE, N.J. 08857 • TELEPHONE: (908) 727-2232
FAX: (908) 727-2653

July 29, 1996

Dr. Janet Anderson
Product Manager, Team 90
Office of Pesticide Programs (APPL)
Document Processing Desk (H7504C)
Environmental Protection Agency
401 M Street, S. W.
Washington, D.C. 20460

440734-00

Reference: Application for Registration of NEU 1165M
EPA File Symbol 67702-G

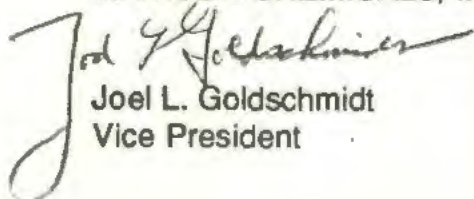
Dear Dr. Anderson

Madison Chemicals, Incorporated ("Madison") is hereby submitting the enclosed product chemistry data on its iron phosphate technical product in support of W. Neudorff GmbH KG's ("Neudorff's") application for registration of its "NEU 1165M" end-use product, EPA File Symbol 67702-G. Neudorff will be using iron phosphate (Ferric Orthophosphate) as the active ingredient in its product.

Please note that Madison should be listed as the original data submitter, or owner of these data.

Feel free to call me should you have any questions.

Yours truly,
MADISON CHEMICALS, INC.


Joel L. Goldschmidt
Vice President

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Madison Chemical Company
P.O. Box 175
Old Bridge, New Jersey 08857

2. Regulatory action in support of which this package is submitted:

Submission of data in support of W. Neudorff GmbH KG's application for registration of NEU 1165M product; EPA File Symbol 67702-G

3. Transmittal Date: July 29, 1996

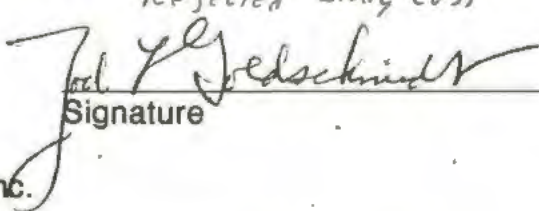
4. List of studies submitted:

Volume 1 Administrative Materials

Volume 2 Product Chemistry: Product Identity and Composition
44073401

Volume 3 Product Chemistry: Analysis and Certification of Product Ingredients
Rejected Study (03)

Company Official: Joel L. Goldschmidt
Vice President


Signature

Company Name: Madison Chemicals, Inc.

Company Contact: Joel L. Goldschmidt

Telephone: (908) 727-2225